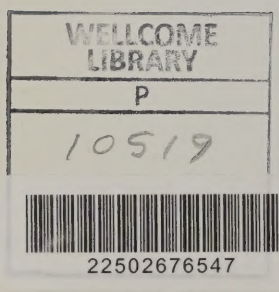


ERRORS IN THE CARE AND TREATMENT OF A YOUNG WOMAN WITH DIABETES

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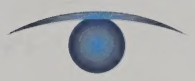
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THE HEALTH SERVICE
OMBUDSMAN

Errors in the Care and Treatment of a young woman with Diabetes

1st REPORT – SESSION 2000-2001

Presented to Parliament Pursuant to Section 14(4)
Of the Health Service Commissioners Act 1993

Ordered by
The House of Commons
To be printed on
6 December 2000

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Foreword

In September 2000, I completed the last of three investigations relating to the care of a young woman, Ms J. I have decided to publish the reports of those investigations together because I believe they illustrate lessons that may be learned about the management of a common condition: diabetes. This was not, however, a common case. Diabetes is a serious and life threatening illness: correctly managed, the risk of premature death and complication can be substantially reduced. Yet Ms J died.

A summary of the events, and of my findings and recommendations appear on pages ii-iv. Subsequent pages contain the full text of my investigation reports and the report of an Independent Review Panel, which considered one of the complaints about Ms J's care. The names of the patient, her brother (who made the complaints) and the doctors have been removed in order to preserve confidentiality. I hope they will provide useful material for health professionals, educationalists and those involved in supporting and caring for people with diabetes.

The report is laid before Parliament in accordance with section 14(4)(b) of the Health Service Commissioners Act 1993. Two of the investigations relate to the health service in Wales; although the events pre-date devolution of powers to the National Assembly for Wales, I have provided a copy of the report to the National Assembly.

M S Buckley
Health Service Ombudsman for England

December 2000

Summary

The events

In February 1996 Ms J, who was 18 years old, went to see her GP because she felt faint after mid-day meals. The GP tested her blood and found signs that she had developed diabetes. He referred her to see a consultant endocrinologist at Halton General Hospital and made arrangements for Ms J's diabetes to be monitored by the practice.

Ms J saw the consultant for the first time in July 1996, when he recorded a diagnosis of mature-onset diabetes in youth (MODY). Ms J saw the nurse specialist in diabetes that day, and several times over the next nine months.

In July 1997 Ms J planned to attend a family occasion in Wales. Feeling a little unwell, she went to her GP on 16 July complaining of muscle pain and lethargy. He recorded some limb girdle weakness in her shoulders and thighs, and a 'borderline' thyroid hormone level: he contacted the consultant after this consultation. Ms J travelled with her fiancé to Wales on 18 July. Feeling much worse when she arrived there, Ms J consulted a local general practitioner, Dr B, the next day, 19 July. Ms J explained that she had MODY and said that she had had stomach pain, sickness and vomiting for a few days. The GP did not test her blood or urine: he recorded a diagnosis of gastritis and prescribed an anti-nausea medication.

Ms J continued to feel very unwell: so much so that she and her fiancé cut short their stay and drove home on 20 July. That day and the next, Ms J consulted GPs at her home practice. Both concurred with the diagnosis given by Dr B, the GP in Wales: they, too, did not test her blood or urine. Ms J's parents called the GP practice a third time, on the morning of 22 July saying that Ms J had been delirious. The GP asked them to test Ms J's blood sugar, but they were unable to do so. The GP arranged Ms J's immediate admission to Halton General Hospital.

Medical staff quickly diagnosed diabetic ketoacidosis, and identified, at the same time, an unusually low level of sodium in her body. Ms J was clearly very unwell: treatment began and Ms J was admitted to the intensive care unit. Ms J remained unwell, and later that day began to complain of a severe headache. The simple pain relief given seemed to help only for a short time and Ms J continued to complain of a very severe headache. Ms J collapsed in the early hours of 23 July, soon requiring full life support. A CT scan of her brain revealed cerebral oedema. Ms J died on 31 July, from cerebral oedema and diabetic ketoacidosis.

Complaints about Ms J's care

Ms J's family complained about several aspects of her care:

- that the diagnosis of mature-onset diabetes in youth was incorrect;
- that insufficient information had been given to Ms J about the management of her diabetes, and in particular the effect of minor illness. They complained that she had not been taught 'sick day rules', that is, blood should be tested more frequently in the event of even a minor illness, as it may drive sugar levels in the blood to a dangerously high level. They also said that she had been wrongly advised that she need not test her blood while on holiday;
- that the GP Ms J consulted in Wales should have tested her urine, at least, and arrived at the wrong diagnosis because he did not do so;
- that the GPs at Ms J's home practice should have tested her urine, at least, and arrived at the wrong diagnosis because they did not do so;
- that when Ms J was admitted to Halton General Hospital, her care and treatment were inadequate, and particularly that excessive administration of fluids caused the cerebral oedema that led to her death;
- that the Independent Review Panel convened to examine the complaint about Ms J's care at Halton General Hospital said that she suffered a 'denial reaction' to the diagnosis of diabetes, and that was wrong, and unjust.

The Ombudsman conducted three investigations into Ms J's care. He investigated the care provided by Dr B, and that provided at Halton General Hospital. He also investigated the way that the Independent Review Panel convened by North Wales HA had reached the conclusion it had about Dr B's care. He was not asked to investigate the care provided by Ms J's 'home' GPs: that had been done by Independent Review Panels, which had criticised the care provided to her by them on 20 and 21 July 1997.

Findings

The Ombudsman found as follows:

(a) The consultant endocrinologist had recorded the diagnosis of MODY precipitately: the diagnosis was wrong; and Ms J most probably had slow onset type one diabetes. It was not possible to determine the full extent of information given to Ms J because the clinical notes lacked sufficient detail. The Ombudsman said that, while the standard of clinical notes was not below that often found, it was clearly not good enough.

(b) It would have been good practice if Dr B had tested Ms J's urine, and his record keeping was not comprehensive enough, nor in keeping with good practice. This was not the conclusion reached by the Independent Review Panel which examined the complaint against Dr B. The Ombudsman found that the Panel failed to reach a conclusion about the standard of care provided or to explain its reasoning. It also left Dr B with no clear statement as to whether he had acted reasonably and, if not, how he might improve his practice.

(c) Ms J had the right to expect better of Halton General Hospital NHS Trust and its staff. In particular:

- Inadequate steps were taken to monitor Ms J's fluid balance, which included the failure to insert a central venous pressure line.
- Her care was divided between two consultants. This led to a degree of confusion, lack of focus on a care plan, and a lack of clear leadership to doctors still in training.
- Nursing staff paid inadequate attention to Ms J's complaint about headache and to her family's expressed concerns about her condition. There was also evidence of inadequate monitoring, record keeping, and communication with medical staff.
- While Ms J's treatment plan was consistent with the hospital's protocol for managing diabetic ketoacidosis, medical and nursing staff did not re-assess the relevance of the plan in the light of clinical circumstances. Ms J's condition did not improve as would have been expected, yet the approach to her treatment was not reviewed by a senior member of the medical staff
- The Independent Review Panel was wrong to say that Ms J had a denial reaction. The Ombudsman found evidence that Ms J was not 'in denial': indeed this was a complex concept that had been treated unwisely by the Panel.

Recommendations and responses

NHS staff and organisations involved in these complaints made a number of changes to practice both in the course of, and in response to, the Ombudsman's investigations. They included routine urine testing for people with diabetes consulting with Dr B, and in respect of Halton General Hospital:

- changed practice on clinical note-making on the part of the nurse specialist in diabetes and a revised education procedure for young people with diabetes
- the appointment of a second consultant with a special interest in diabetes at Halton
- development of a range of services for people with diabetes, including foot health, retinopathy, specialist nurse, and young persons' clinics
- improvements to literature for people with both type 1 and 2 diabetes, and to nursing documentation
- revised management arrangements in the Intensive Care Unit

- revised policy on managing diabetic ketoacidosis
- review of ITU nurse staffing levels in preparation for the Unit's transfer to a purpose-built critical care facility
- changed management protocol for diabetic ketoacidosis to include reference to cerebral oedema.

All those complained about accepted the Ombudsman's findings, apologised for the shortcomings revealed by the investigations, and agreed to implement the following recommendations made by him:

Dr B

Dr B should keep full clinical notes for all his patients, including positive and negative findings from examinations.

Halton General Hospital

(a) the revised education procedure for people with diabetes should be the subject of audit;

(b) nurse specialists should include the items of information and education provided to patients in the clinical record - not for defensive purposes, but to assure effective communication between health care professionals;

(c) the Trust should ensure that all people with diabetes, regardless of type or severity, are familiar with 'sick day rules' and when to contact the diabetic clinic for advice;

(d) the Trust should reflect on nursing care provided to Ms J as part of a staff development programme.

Conclusion

In the conclusion to the third investigation, the Ombudsman said:

'There is no doubt that type 1 and type 2 diabetes are serious life threatening conditions. Equally, there is no doubt that if they are correctly managed the risk of premature death and complications can be substantially reduced. Yet Ms J died. This investigation needs to be seen in the context of those previously conducted by my office and through the NHS complaints procedure into the entire course of Ms J's treatment and care. From this it is clear that a number of mistakes were made beginning with the initial, unduly definite, diagnosis of type 2 diabetes. Avoiding any one of these mistakes would have improved Ms J's chances of survival. It is not possible for me to say that one or more of these mistakes individually led to her death: but taken together they almost certainly did. If, for example, the diagnosis had been correct, or expressed with sufficient caution; if we could be certain that Ms J received the information and education she needed; if any one of the three GPs involved in her care had tested her blood or urine; or if Ms J had had impressed upon her, in no uncertain terms, that she must test her blood daily when unwell, had done so and reported untoward results, she might have survived.

'This investigation revealed that Ms J's inpatient care could have been more expertly co-ordinated and that she had a right to expect better from the trust and its staff. I cannot say with any certainty what contribution, if any, these failings made to the tragic outcome of this case.

'An important lesson is the need for all those involved in diabetic care, not least patients themselves, to be aware that it is essential to test blood glucose and urine ketones more frequently during an intercurrent illness, whatever the type or severity of diabetes. This simple measure could have saved Ms J: I hope it will save others.'

Office of the Health Service Ombudsman
December 2000

Glossary of Terms

Technical term	Meaning
acidosis	an abnormally high concentration of acid in the blood
catheter (urinary)	a flexible tube inserted into the bladder to allow the removal of urine
Cerebral oedema	an excess of fluid in the brain
CVP - central venous pressure	the pressure within the central veins returning blood to the heart
dehydration	loss or deficiency of water in body, tissues and blood
diabetic ketoacidosis	an excess of acid and ketones - an organic compound - which may be present in the body tissues and fluids, which develops in diabetics when their condition is getting out of control and may indicate approaching coma
fluid balance chart	a chart which records and sums a patient's input and output of liquid on a daily basis
gastritis	inflammation of the lining of the stomach
glycosuria	glucose in the urine
HbA1c - haemoglobin	an indirect measure of the effectiveness of blood glucose ('sugar') control in past two weeks
hyperglycaemia	an excess of sugar [glucose] in the blood
hypoglycaemia	a low concentration of glucose in the blood
hyponatraemia	a low concentration of sodium in blood, usually as a result of a relative excess of water but sometimes a result of salt loss
hypotension	low blood pressure
hypothyroid	reduced thyroid function
ketones	substances arising in metabolism when there is insufficiency of insulin
mass lesion	a solid abnormal appearance on scanning
pituitary apoplexy	collapse as a result of severe pituitary gland failure
subarachnoid haemorrhage	haemorrhage on the surface of the brain
subclavian	under the collar bone
tachycardia	rapid heart beat
type 1 diabetes	insulin dependent diabetes - requires treatment with insulin
Type 2 diabetic	non-insulin-dependent diabetic, whose pancreas has retained some ability to produce insulin but this is inadequate for the body's needs

Chapter 1 • Investigations

Case No. W.138/97-98

The care provided to Ms J by Dr B, a general practitioner

Complaint against

Dr B, a general practitioner in the North Wales HA area

Complaint as put by Mr J

1. The account of the complaint provided by Mr J was that on 18 July 1997, his sister, Miss J, travelled to a holiday centre for a short holiday. During the preceding few days she had complained of muscle pain and lethargy. She again felt unwell on the journey; and on the following day, 19 July, she attended Dr B's surgery at the centre. Dr B examined Miss J, who complained of stomach pain and nausea and that she had been vomiting for two days and was slightly constipated. She also said that she had been diagnosed as having Mature Onset Diabetes of the Young (MODY) (a form of non-insulin dependent diabetes) and had not tested her blood glucose levels. Dr B diagnosed gastritis and prescribed Maxolon, an anti-nausea medication. Miss J continued to feel unwell and, on 20 July, returned to her home in Widnes, where she was seen by a locum GP (the second GP) on 20 July and her own GP (the third GP) on 21 July. She was admitted to hospital on 22 July suffering from diabetic ketoacidosis (an excess of acid and ketones - an organic compound - which may be present in the body tissues and fluids, which develops in diabetics when their condition is getting out of control, and may indicate approaching coma). She died on 31 July.

2. Mr J complained to the practice about the treatment Dr B gave his sister and subsequently requested an independent review of his complaint. The independent review was held on 6 January 1998; but Mr J remained dissatisfied. The conduct of the independent review is the subject of a separate investigation by the Commissioner.

3. The matter subject to investigation was that Dr B's clinical management of Miss J's condition was unsatisfactory in that:

   (a) he took insufficient steps to diagnose and treat her condition, in particular, he failed to test glucose and ketone levels; and

   (b) he failed to ensure that she had sufficient knowledge to manage her diabetes in the light of her symptoms.

Investigation

4. The context of this investigation is that Dr B was the first of three GPs who saw Miss J between 19 and 22 July 1997, when she was admitted to hospital. The actions of the two GPs who saw her after her consultation with Dr B were subject to complaint by Mr J: in both cases the Health Authority commissioned independent reviews to consider the adequacy of the care they gave. Dr B's actions were also subject to independent review, following which Mr J remained dissatisfied and approached the Commissioner. Dr B came to the same diagnosis as the two GPs who saw Miss J later. The actions of the two GPs were criticised by the independent review panels. The panel which considered the actions of the second GP who saw Miss J on 20 July, concluded that he should have tested her blood and in failing to do so fell below the standard of a reasonable GP. The panel that considered the actions of the third GP, who saw her on 21 July, concluded that he should have established her current blood sugar level, preferably by checking it himself, and that because he failed to do this his standard of care was not of an acceptable level.

5. The statement of complaint for the Commissioner's investigation of the complaint against Dr B was issued on 1 April 1998. I obtained Dr B's comments on the statement; and relevant documents were examined. One of the Commissioner's investigating officers took evidence from Mr J, Miss J's fiancé and

Dr B. Two external professional assessors (the Commissioner's clinical assessors) were appointed to give independent advice on the clinical issues central to this case, which are about whether, when he saw Miss J on 19 July, Dr B acted in a way consistent with reasonable clinical practice (see paragraph 7). The assessors have expressed an opinion on the reasonableness of Dr B's actions given the information he had or might have elicited when he saw Miss J. They have not, rightly, taken account of subsequent events, including Miss J's later care in hospital. The assessors were unable to say whether Miss J would have survived had Dr B acted differently. The assessors' report is at Appendix A. A note on technical terms used recurringly in this report is at Appendix B. I have not put into this report every detail investigated; but I am satisfied that no matter of significance has been overlooked.

Complaints (a) - Dr B took insufficient steps to diagnose and treat Miss J's condition, in particular, he failed to test her glucose and ketone levels; and (b) - he failed to ensure that Miss J had sufficient knowledge to manage her diabetes in the light of her symptoms.

Relevant legislation and national guidance

6. The National Health Service (General Medical Services) Regulations 1992, include at section 26(1) that "A person requiring treatment who .... is not on the list of a doctor providing general medical services in the area of the locality where he [she] is temporarily residing .... may apply to any doctor providing services in the locality in which he [she] is temporarily resident to be accepted by him as a temporary resident". The regulations interpret `treatment' to mean `medical attendance and treatment .... ' but to exclude health surveillance, contraceptive, maternity, medical and minor surgery services.

7. Schedule 2 of those regulations contains the terms of service for doctors, which include:

`Where a decision whether any, and if so what, action is to be taken under these terms of service requires the exercise of professional judgment, a doctor shall not, in reaching that decision, be expected to exercise a higher degree of skill, knowledge and care than -

` .... that which general practitioners as a class may reasonably be expected to exercise.'

Professional guidance

8. Guidance from the General Medical Council entitled `Good Medical Practice', in the edition published in 1995 (before the events subject to complaint), describes good clinical care as including:

`- an adequate assessment of the patient's condition, based on the history and clinical signs including, where necessary, an appropriate examination;

- providing or arranging investigations or treatment where necessary .... .

- [keeping] .... clear, accurate, and contemporaneous patient records which report the relevant clinical findings, the decisions made, information given to patients and any drugs or other treatment prescribed.'

Evidence of Mr J and Miss J's fiancé

9. On 23 October 1997, **Mr J** wrote to Dr B's practice manager making a formal complaint against Dr B. He said that Miss J had presented at Dr B's surgery with signs of hyperglycaemia (an excess of sugar in the blood) - vomiting, nausea, stomach pains and thirst. She told him she was diabetic, but Dr B failed to carry out a blood or urine test.

10. On 23 January 1998, Mr J complained to the Commissioner that his sister had attended Dr B's surgery as a temporary resident, and clearly identified herself as a diabetic who had been vomiting for two days. Mr J wrote:

`Knowing that [Miss J] was a diabetic Dr B failed to enquire about or test diabetic control. The only safe way for Dr B to have proceeded was to have actually tested blood glucose levels and urine ketone levels .... knowing [Miss J] was a diabetic he failed to ensure that [Miss J] understood the implications of this vomiting and understood how to manage her diabetes during illness. These measures are widely accepted as good clinical practice ....

`It is our position that to fail to test diabetic control in an identified diabetic patient if the patient is vomiting .... is acting without regard for the danger of the loss of diabetic control which can be fatal. We feel that .... had Dr B checked diabetic control .... he would have found definitive signs of hyperglycaemia and diabetic ketoacidosis. Had this been the case and [had] appropriate treatment been commenced then .... [Miss J] would be alive today.'

11. When interviewed Mr J said that his mother telephoned him on 20 July (the day his sister

returned home from the holiday camp), and said that Miss J was unwell and had been seen by a doctor (the second GP). His mother had put her concerns about a link between diabetes and her daughter's illness to the doctor, but the second GP said that her daughter had a viral infection. On 21 July, Mr J's mother told him that a doctor (the third GP) was coming to see his sister. On 22 July his mother told him that his sister was being taken to hospital. Mr J visited his sister in the intensive care unit (ITU). She told him that she had seen a doctor whilst on holiday and had told him that she was diabetic, was vomiting, and had tummy pain. The doctor (Dr B) had not told her what he thought was wrong, but had given her some medicine. The next day Mr J spoke to Miss J's fiancé, who told him that he had accompanied her to see a doctor whilst on holiday. Mr J told the investigator that Dr B knew that Miss J was a diabetic and was vomiting. He said that Dr B asked her whether she was testing her blood and she said she was not. [Note: a test record maintained by Miss J and seen by the investigating officer records that Miss J did test her blood sugar levels. Her last recorded reading was taken on 14 July 1997 and was 11 millimoles]. Mr J thought that `giving safety net advice' [`come and see me if you are not better'] was not enough for a diabetic at risk of losing diabetic control. Mr J considered that Dr B should have tested Miss J's blood and urine and ensured that she knew how to manage her diabetes during illness.

12. On 23 November 1997, **Miss J's fiancé** (the fiancé) made a signed statement which includes:

`On the way to the holiday park [Miss J] .... began to feel ill with tummy pains and feeling sick. Shortly after arrival at the park [Miss J] was actually sick a number of times and was unable to keep any food or drink down. The minute she ate or drank it just came back.

'As she had not got any better I asked her to go to the doctor's at the camp ....

` .... we went into the room .... the doctor asked [Miss J] what the problem was. [Miss J] told him that she was a diabetic, she told him she was MODY and was diet controlled .... that she had been feeling unwell for 2 days, she had been feeling sick, she had vomited, she had a tummy ache and was feeling thirsty. I added that she had been unable to keep any food or drink down .... the minute she ate or drank she would throw it straight back.

` .... At no time did the doctor enquire about [Miss J's] diabetes nor did he carry out a blood test or anything really .... The doctor certainly did not tell [Miss J] to come back and see him nor did he tell her that she could call him out in the night if her illness continued ....

`At about 4 o'clock in the morning on the 20th July 1997 [Miss J] woke up constantly vomiting and crying .... I took her home.'

13. When interviewed, the fiancé said that he and Miss J went to the holiday centre with his cousin, his cousin's partner, and their baby to celebrate his cousin's 21st birthday. Miss J had begun to complain during the car journey that she was feeling `a bit ill'. They arrived at the centre at 10.30 am, got their keys, unpacked, and then walked around to see the shops and arcade. They went to the centre's club in the evening. Miss J was feeling a little unwell, but did not want to spoil the evening and so `put up with it'. They left the club early because of the baby and went to bed. During the early hours of the morning Miss J was `being sick constantly'. The fiancé did not see Miss J being sick, but heard her retching. He persuaded her to visit the camp doctor, and they walked to the surgery at about 4.00pm. Miss J filled out a form. In the surgery she told the doctor that she had been vomiting, was `constantly thirsty', and could not keep anything down. The fiancé told the doctor that Miss J's diabetes was diet-controlled. Dr B asked no questions about Miss J's diabetes and did not ask her whether she tested her blood or urine. Dr B examined Miss J's abdomen and she told him that some areas were tender to the touch. She said she was slightly constipated. Dr B gave Miss J a prescription, instructed her to take the syrup, and said that she `would be right as rain in the morning'. Dr B did not give Miss J his diagnosis, but the fiancé told the investigating officer that he thought he mentioned `gastritis' and that that was why he was checking her stomach. Dr B did not tell Miss J what to do if she continued to feel unwell.

14. Miss J took the medicine, but it did not help. She continued retching, and was either sick or retched whenever she tried to eat or drink. At about 4 o'clock the following morning Miss J awoke and was continuously vomiting and crying. Her fiancé heard her retching; and she asked him to take her home. The fiancé said that he did not know how to contact Dr B: there was no notice in their caravan, and he thought the surgery would not open again until 4.00pm. He took Miss J home.

Documentary evidence

15. Dr B completed a temporary resident record for Miss J, as follows (see explanations in paragraph 24):

`Vomiting 2/7 ab[domen] (tick)
`BO [bowels open] (tick) M.O.D.Y.
`Rx [treatment] Maxolon Syr[up]'

`21/8/97 - message from brother
`Mr J ....
`S/B [seen by] locum Widnes 20/7
` own GP 21/7
`admitted 22/7
`Died in hosp[ital] 31/7 .... '

16. On 20 July 1997, Miss J was seen at home by a locum

GP (the second GP). He recorded:

> `History
> `Abdo[minal]-pain : vomiting since last Fri[day]
> `Bowels (tick)
> `Diabetic on diet control
>
> `Clinical examination
> `Anaemia (nil) Jaundice (nil)
> `Well hydrated
> `Abdo[minal] tenderness [a diagram sited pain in the lower left quadrant] no guarding, no lumps LKKP [no lumps felt in liver, spleen or kidneys]
> `Temperature 35.7C Pulse 80bpm [beats per minute] BP [blood pressure](no entry).
> `Diagnosis - Gastritis'

17. On 21 July 1997, Miss J was attended by the third GP who recorded the following in her clinical notes:

> 21.7.97 Vomiting 3/7. Given stemetil liquid by locum. Makes her sick. O/E [on examination] Not dehydrated. [Abdomen] soft non tender. RS [respiratory system] NAD [no abnormality detected] No genito-urinary or gastrointestinal symptoms. RBS [glucose level] around 7. PU [passing urine] normally. Diagnosis Gastritis.'

18. The transcript of evidence to the independent review panel which considered Mr J's complaint about the third GP includes a statement by him that he did not associate Miss J's symptoms with diabetes because she did not look ill, did not appear to be vomiting, her breath did not smell of ketones, she was not clinically dehydrated, she denied passing large amounts of urine, and was normal mentally. Miss J's mother told him that her daughter's blood sugar was around 7 millimoles per litre.

19. The post-mortem report, dated 1 August 1997, lists Miss J's cause of death as acute cerebral oedema [an excess of fluid in the brain] and diabetic ketoacidosis.

20. The conclusions of the report of the independent review of Mr J's complaint against Dr B include:

> *`.... whilst MODY was recognised in [Miss J], no specific steps were taken by Dr B to establish the precise nature of [Miss J's] diabetic condition ....*
>
> *`If [Dr B's notes] do not record relevant negative findings which were drawn [by him] then we conclude that they would fall below the requirements of good practice.'*

Dr B's evidence

21. In his formal response to the Commissioner, conveyed in a letter from Solicitors, **Dr B** said that he had a `normal, intelligent' conversation with Miss J about her illness. She told him that she had been vomiting on and off since the previous day, that she was a diet controlled diabetic, and that MODY had been diagnosed by a hospital consultant. Dr B explained to her that an upset stomach could be a sign that her diabetes was not under proper control. He wanted to establish, therefore, whether she had any symptoms of ketoacidosis or hyperglycaemia. He asked her whether her diabetes was `playing up'. Miss J told Dr B that she was not testing her blood sugar levels. Dr B added:

> *'Miss J did not tell [me] she had "tummy pain" and "thirst" as set out in Mr J's letter .... If she had complained of these symptoms [I] would immediately have suspected a diabetic cause .... and arranged further investigation. These are classic symptoms of diabetes which simply were not present at the time .... [I] did specifically ask her whether she was drinking more than normal and whether she was passing water more often than normal. Her answer .... was no .... '*

22. The statement said that Dr B examined Miss J's abdomen which was unremarkable. She said that she did not have any pain; that her bowels had been open; and that she had had no diarrhoea. She was able to climb on and off the examination couch without difficulty. Dr B smelt Miss J's breath and excluded any smell of ketones and fetor (an unpleasant smell). She was not dehydrated and did not appear lethargic. Dr B's clinical assessment was that her diabetes was not relevant to the presenting complaint of vomiting. She denied any symptoms associated with hyperglycaemia or ketoacidosis. Dr B was also reassured by the diagnosis of MODY because type 2 diabetics (non-insulin dependent) were very unlikely to develop a ketoacidotic state in the absence of severe illness or infection. He said:

> *'It is admitted that [I] did not test glucose and urine ketone levels but it is denied that the patient's clinical condition or history given at the time of the consultation required such steps'.*

23. Dr B also denied that he failed to ensure that Miss J had sufficient knowledge to manage her diabetes in the light of her symptoms.

24. Dr B told the Commissioner's investigating officer that his practice had an agreement with the holiday centre to provide medical cover seven days a week. When Miss J walked into his surgery she did not appear at all ill. Dr B had not been called out to visit Miss J, as he would have expected had she felt very ill. Dr B said that Miss J was not sick whilst in his surgery and was well enough to fill out a form on arrival. She was not clutching a bowl or receptacle to be sick in, as Dr B would have expected if she was nauseous. Miss J said that she had been vomiting and was MODY. Dr B questioned her about her diabetic control. She was unable to tell him what her sugar

level was. Dr B asked about polydipsia (excessive thirst) and polyuria (excess urine production) and used this as a crude screening process to exclude hyperglycaemia in a type 2 diabetic. He asked Miss J if she was thirsty and she said no. If she had been a true type 2 diabetic Dr B believed that she would have been very unlikely to develop diabetic ketoacidosis in the absence of acute infection or serious illness - which she did not have. Had Miss J appeared ill, Dr B said that he would have tested her blood sugar; but he saw no indication that such a test was needed. Dr B said he was surprised when Miss J told him that she did not test her own blood or urine; and he suggested to her that she should contact her GP about this as, if she was a true type 2 diabetic and did not monitor her sugar levels, she might develop problems in the long term. Dr B said that, with hindsight, he would have tested her; but at the time she looked well, the vomiting appeared to have stopped, and she appeared quite comfortable. She was a type 2 diabetic MODY, and Dr B did not consider her to be at particularly high risk of developing diabetic ketoacidosis.

25. Dr B said that he wrote short notes of the consultation as an 'aide memoire'. He was on call that weekend, and so could have seen Miss J again if she had needed a doctor. Dr B usually recorded important facts in his notes. The degree of detail varied from patient to patient according to need. He explained that, in Miss J's case, 'abdomen - tick' (see paragraph 15) meant that nothing abnormal had been found; if her abdomen had been tender he would have drawn a diagram to indicate where. `BO (bowels open) - tick' meant that there was no diarrhoea or constipation. `Vomiting 2/7' meant that she had been vomiting for two days - the day of the consultation and the day before. Dr B said that he had diagnosed gastritis based on a history of vomiting with no obvious cause, where the vomiting had ceased and the patient recovered - which Dr B believed was what appeared to have happened in Miss J's case. He had established during their conversation that she was keeping some fluid down and did not appear dehydrated. Dr B said that he smelt Miss J's breath during the examination to exclude the presence of ketones or fetor. At the time of the consultation it seemed reasonable not to test Miss J's blood sugar. Dr B said that he was now `extra cautious' and tested all diabetics he saw. However, his judgment at the time was that there was no need for him to test Miss J.

Clinical Assessors' advice

26. The Commissioner's assessors' report (at Appendix A) concludes:

`- Dr B took a reasonable history for someone who at the time of being seen did not present as particularly ill;

- Dr B should have recorded both positive and negative findings in view of Miss J's past medical history and diagnosis;

- There is a range of views as to whether urine or blood should be tested for glucose in a diabetic with a history of vomiting. If it is accepted that Miss J was not particularly ill at the time she was seen it may not have been necessary in her case. However, it would probably be considered good practice to test urine in a diabetic patient, presenting with vomiting, when this was not being undertaken by the patient;

- Dr B's note-keeping was not comprehensive enough;

- It was not Dr B's responsibility to educate Miss J about diabetic management.'

Findings (a)

27. Mr J has complained that Dr B should have tested Miss J's urine and blood when he saw her as a temporary resident patient at the holiday centre on 19 July 1997 and that, had he done so, she might be alive today. I recognise the distress and anger the family have experienced as a result of that belief. My findings in this case focus on whether Dr B did all that could reasonably be expected of a competent general practitioner in the circumstances.

28. Having accepted Miss J as a temporary patient at the holiday centre, under the provisions of section 26(1) of the General Medical Services Regulations (paragraph 6), Dr B had a responsibility to provide no less a standard of care and treatment to her than to a patient seen in his own practice. Miss J presented on 19 July as a patient Dr B did not know and who told him that she had been vomiting and was diabetic in the form of the relatively unusual condition MODY.

29. There is no dispute that Dr B did not test Miss J's blood sugar or urine. His reason for not doing so was that MODY carried a low risk of ketoacidosis in the absence of severe illness or infection, and he did not consider that Miss J presented as particularly ill when he saw her. It is certainly true that Miss J was able to go out with friends the night before; was able to walk to the surgery; and was not sick while there. Had Miss J not been diabetic it is unlikely that there would have been reason to question Dr B's diagnosis and treatment of what he deduced was gastritis - a diagnosis also made later by the second and third GPs (paragraph 4). However, Dr B knew that Miss J was diabetic and was unwell, and he believed that she was not testing her own blood sugar. My findings must turn on whether he paid sufficient attention to these factors when he saw her.

30. There is a conflict of evidence between Dr B's and the fiancé's accounts of what happened in the course of the consultation on 19 July. Dr B maintained that he considered the possibilities of hyperglycaemia and

ketoacidosis, but excluded them on the basis of questions he put to Miss J and the answers she gave; the fact that she was not dehydrated, had no smell of ketones on her breath and no report of thirst or excessive urine production; and the diagnosis of MODY. Dr B said that Miss J told him that she was not testing her blood sugar levels. On the basis of the history he took, Dr B diagnosed gastritis, for which he prescribed Maxolon and advised Miss J to return or call him out if she continued to feel unwell. The fiancé said that Dr B asked no questions about Miss J's diabetes and that she gave a different account of her symptoms.

31. Unfortunately, Dr B did not make a full record of the questions he asked Miss J and the answers she gave. Dr B said that his practice was to vary the content of his notes according to the needs of each patient but to record important detail. In Miss J's case the sole reference to diabetes in Dr B's notes is `MODY'. His notes are brief in the extreme (paragraph 15) indicating negative findings only by a tick against `abdomen' and `bowels open'. There is no tick against `MODY' to indicate that Dr B excluded symptoms associated with diabetes. These limitations make it impossible for me to decide between the two accounts of what happened at the consultation. The Commissioner's assessors have advised that Dr B's note-keeping was not comprehensive enough and that he should have recorded both positive and negative findings, in view of Miss J's past medical background and diagnosis. I agree; and I **recommend** that Dr B should ensure that he keeps a full record for all his patients, including temporary residents, which includes both positive and negative findings.

32. Should Dr B have tested Miss J's blood sugar and ketone levels? The Commissioner's assessors advise that there is a range of views within the medical profession on the need to test routinely diabetic patients who present with vomiting. They add that if it is accepted that Miss J did not appear particularly ill at the time she was seen, it follows that it might not have been necessary to test her blood and urine. However, Dr B was not faced with a routine situation. Miss J was seen as a temporary patient, and Dr B had no more information available than he elicited in the course of the consultation. On the question of testing blood sugar, Dr B says (paragraph 22) that Miss J said that she was not testing her own blood or urine, and that he was surprised about that. Although the investigation has revealed a record (paragraph 11) that Miss J did test herself, I have no reason to think that Dr B knew that. At best (according to his own account) he was surprised to be told that she had not tested. At worst (according to the fiancé's account) the subject did not come up at the consultation. Whichever account is true, according to the Commissioner's assessors it would have been good practice for Dr B to have acted with greater caution and at least tested Miss J's urine, in the absence of knowledge that Miss J was testing herself. I accept that advice. I conclude that it would have been good practice for Dr B to have tested Miss J; and I uphold this aspect of the complaint to that extent. I note that Dr B now routinely tests the blood sugar of diabetic patients.

33. In upholding this aspect of Mr J's complaint I should like to make two observations. First, neither I nor the Commissioner's assessors are able to say whether had Dr B, or any of the GPs who saw Miss J, acted differently she would have been alive today. To do so would be speculative for the reasons set out in paragraphs 4 and 5 above. Secondly, the totality of Miss J's care in the period between 19 July and 31 July, when sadly she died, has been the subject of investigation through the complaints procedure or will be the subject of investigation by the Commissioner. He intends to consider when all the investigations are complete whether there are issues related to the general question of diabetic care which he should draw to the attention of the Secretary of State. He, his advisers and the medical profession might wish then to consider whether there is a need for review of the guidance on professional practice in the management of acute diabetes.

Findings (b)

34. Mr J also complained that Dr B had a responsibility to ensure that Miss J understood how to manage her diabetes during an episode of illness. Dr B disagreed, and said that he advised Miss J to speak to her own GP about testing her blood glucose because of the risk of long-term complications for type 2 diabetics. He also said that he told Miss J to come back to see him, or call him out, if she remained unwell. The fiancé denied that Dr B gave advice on either matter. Again, in the absence of contemporaneous records, it is not possible to decide between these accounts. The Commissioner's assessors have advised that, in their view, it was not Dr B's responsibility to attempt to provide diabetic management advice to Miss J. I agree. She was a temporary patient who was feeling unwell and, therefore, might not have been in the best position to be receptive to or retain such information. I do not uphold this aspect of the complaint.

Conclusion

35. This report is of one of a series of investigations into aspects of the care of Mr J's sister and how his complaints were handled. I have set out my findings in paragraphs 27 to 34 on his complaints against Dr B. Dr B has agreed to implement my recommendation in paragraph 31 and has asked me to convey to Mr J - as I do through my report - his apology for the shortcomings I have identified.

March 1999

Appendix A

Report by the Professional Assessors to the Health Service Ombudsman for Wales of the clinical judgments of staff involved in the complaint made by Mr J

Professional Assessors

First Assessor

Dr L - MB BS DTM&H D.ObstRGOG

General Practitioner for 29 years
Senior Partner in a four doctor, seaside town practice

Second Assessor

Dr N BSc MB ChB

General Practitioner for 11 years
Senior Partner in a four doctor, inner city practice

Matters considered

36. The matter subject to investigation is that Dr B's clinical management of Miss J's condition was unsatisfactory in that:

a) he took insufficient steps to diagnose and treat her condition, in particular, he failed to test glucose and urine ketone levels (a ketone is a chemical which is present in the urine when diabetes is not in good control); and

b) he failed to ensure that she had sufficient knowledge to manage her diabetes in view of her symptoms.

Basis of report

37. In formulating our report, we have perused a set of documents and reports which have been made available to us by the Office of the Health Service Commissioner, and which have included:

Report of the independent review panel regarding the late [Miss J], dated January 1998.

Papers considered by the independent review panel on 6 January 1998, including:

1. the original complaint
2. the response from the GP, Dr B
3. a copy of the Temporary Resident Clinical Record
4. correspondence requesting the independent review
5. the statement from [the fiancé]
6. additional information to support the complaint by [Mr J]
7. Letter to the Health Service Commissioner for Wales from [Mr J], dated 23 January 1998.
8. Response to the complaint against Dr B, prepared by Solicitors, dated 5 May 1998.
9. Notes of the interview between the Commissioner's investigator and [Miss J's] fiancé dated 29 July 1998.
10. Notes of the interview between the Commissioner's investigator and [Dr B] in the presence of the first and second assessor dated 19 August 1998.

Assessors' comments on the actions of Dr B

38. We have noted that Miss J was diagnosed MODY in July 1996.

On 18 July 1997, Miss J complained of `tummyache' and nausea on a journey to [the holiday centre].

In the early hours of 19 July 1997, Miss J started vomiting.

At 4pm on 19 July, she attended a surgery, and saw Dr B at approximately 4.30pm.

According to the clinical record made by Dr B, Miss J gave a history of vomiting for 12 hours (he actually wrote `vomiting for two days' by which we understand that he meant `yesterday and today').

Dr B noted that she had Maturity Onset Diabetes of the Young.

Dr B noted that her bowels were normal.

Dr B examined her abdomen and found no

abnormality.

We believe that Dr B formulated a diagnosis of gastritis, although this is not recorded in the clinical record.

Dr B prescribed maxolon syrup.

We have noted that Miss J did not vomit whilst with Dr B, and probably did not vomit again until 4am the next morning, when it was decided that Miss J should travel home, rather than call a doctor out at [the holiday centre].

We have noted that there is some discrepancy as to whether Dr B did ask Miss J whether she checked her own blood or urine. Unfortunately, this is not recorded on the clinical record.

We have noted that Dr B neither tested her blood nor urine during the consultation.

Although it is not recorded in the clinical record, there is nothing to suggest that at the time that Miss J was seen, she had ketones.

Conclusion

39. (i) In considering all the evidence, we are of the opinion that Dr B took a reasonable history of someone who, at the time of being seen, was not particularly ill.

(ii) We believe that, in view of her past medical history and diagnosis, Dr B should have recorded both positive and negative findings.

(iii) It would be fair to say that there is a range of views as to whether urine or blood should be tested for glucose in a diabetic with a history of vomiting. If we accept that Miss J was neither particularly ill nor vomiting at the time that she was seen, then it may not have been necessary. However, it would probably be considered as good practice to test the urine in a diabetic patient, presenting with vomiting, when this was not being undertaken by the patient.

(iv) We generally feel that Dr B's note keeping was not comprehensive enough.

(v) We do not feel that it was the responsibility of Dr B to educate Miss J, a temporary resident, consulting when she was not feeling well, on the management of diabetes.

THE HEALTH SERVICE
OMBUDSMAN

7 December 2000

EMBARGOED UNTIL 00.01 HOURS, 7 DECEMBER 2000

PRESS RELEASE

Ombudsman's Report Highlights Errors in Clinical Care of a Diabetic Patient

Three investigations published today as a special report by the Health Service Ombudsman, Michael Buckley, highlight errors regarding the care of Miss J, a diabetes sufferer, who died prematurely aged twenty. Although this was a rare case, the condition is a common one and the report provides lessons for all those involved in diabetic care: especially that diabetics should test their blood sugar regularly through a period of illness.

The investigations examined the clinical care provided by Dr B (a GP in the North Wales Health Authority Area) and Halton General Hospitals NHS Trust, and the conclusions of an independent review panel examining the complaint against Dr B.

The Events Surrounding the Investigation

Miss J was diagnosed as suffering from mature-onset diabetes of the young (MODY) in July 1996. MODY (now known as type 2 diabetes in the young) is non-insulin-dependent, meaning that the sufferer can control the condition through diet alone.

A year after being diagnosed, Miss J began to feel unwell and visited GPs on several occasions, once before going on holiday, once whilst on holiday in Wales and twice on her return. None of the three GPs tested Miss J's blood or urine for signs of loss of diabetic control, and all diagnosed her with gastritis. The day after the third consultation, Miss J was admitted to hospital suffering from ketoacidosis, a dangerous condition relating to insulin-dependent diabetes, and sent straight to the Intensive Therapy Unit. At that point she was seriously ill.

There was confusion in ITU over which consultant was responsible for Miss J's care. In the Ombudsman's view this led to "a degree of confusion, lack of focus on a care plan, and a lack of clear leadership to doctors in training."

Later that day, Miss J's condition had not improved, despite treatment, and she began to complain of a headache. The Ombudsman found that "Nursing staff did not pay enough attention to Miss J's complaints about a headache or the concerns expressed by her family. They also failed to reassess Miss J's care plan in the light of her lack of progress or review her treatment with a senior member of the medical team."

Miss J collapsed in the early hours of the following morning, and was put on life support. A CT scan of her brain revealed cerebral oedema, a swelling of the brain inside the skull. This is a rare, but known side effect of ketoacidosis. Miss J died on 31 July 1997.

The Ombudsman's Findings

The Ombudsman found that the consultant in the diabetes clinic diagnosed MODY too quickly. Miss J was probably suffering from slow onset type 1 diabetes, which develops so as to require insulin over time. Turning to the care given by Dr B, he found that it would have been good practice for Dr B to test Miss J's blood and urine for signs of a loss of diabetic control, and said "his record keeping was not comprehensive enough, nor in keeping with good practice".

Michael Buckley said, "Ms J had the right to expect better of Halton General Hospital NHS Trust and its staff." As well as those concerns highlighted in the summary of events, the Ombudsman found that staff did not take adequate steps to measure Miss J's fluid balance (her input and output of water).

Results

As a result of both the original complaint and the Ombudsman's investigation, several improvements have been made. Dr B now routinely tests the blood and urine of all his diabetic patients; and a number of changes have been implemented at Halton General Hospital. These include: improvements in the standard of clinical notes by the clinical nurse specialist, the appointment of a second consultant with a special interest in diabetes, the development of a range of services for diabetic patients, and improvements to both nursing documentation and the information given out to diabetes patients. The Trust has also revised management arrangements in ITU.

Michael Buckley said: 'Avoiding any one of the mistakes in clinical care by both GPs and Trust staff would have improved Miss J's chance of survival. It is not possible for me to say that one or more of these mistakes individually led to her death: but taken together they almost certainly did.

'....An important lesson is the need for all those involved in diabetic care, not least the patients themselves, to be aware that it is essential to test blood glucose and urine ketones more frequently during an intercurrent illness, whatever the type or severity of diabetes. This simple measure could have saved Miss J: I hope it will save others.'

-ends-

For more information please contact Barbara Batchelor or Lorna Branton - 020 7217 4077.

NOTES TO EDITORS

1. The report is "Errors in the Care and Treatment of a Young Woman with Diabetes" - HC13
2. **NO INFORMATION CAN BE GIVEN ABOUT THE IDENTITY OF THE INDIVIDUALS INVOLVED IN THESE CASES**
3. Press copies of the report are available from the press office – 020 7217 4077 or from 7 December at www.ombudsman.org.uk

Appendix B
Glossary of Terms

Technical term	Meaning
MODY (Mature Onset Diabetes of the Young)	a form of non-insulin dependent diabetes (first used in paragraph 1)
Diabetic ketoacidosis	an excess of acid and ketones - an organic compound - which may be present in the body tissues and fluids, which develops in diabetics when their condition is getting out of control and may indicate approaching coma (paragraph 1)
Hyperglycaemia	an excess of sugar [glucose] in the blood (paragraph 7)
Cerebral oedema	an excess of fluid in the brain (paragraph 17)
Type 2 diabetic	non-insulin-dependent diabetic, whose pancreas has retained some ability to produce insulin but this is inadequate for the body's needs (paragraph 20)

The conclusions reached by the Independent Review Panel that examined the care provided by Dr B

Body complained against

North Wales Health Authority

Complaint as put by Mr J

1. The account of the complaint provided by Mr J is that on 18 July 1997, his sister, Miss J, travelled to a holiday centre for a short holiday. During the preceding few days she had complained of muscle pain and lethargy. She again felt unwell on the journey to the holiday centre and on the following day, 19 July, she attended a surgery held by a GP. The GP examined Miss J, who said that she had stomach pain and nausea, had been vomiting for two days and was slightly constipated. She also said that she had been diagnosed as having mature onset diabetes in youth (MODY) [a form of non-insulin-dependent diabetes] and that she had not tested her blood glucose levels. The GP diagnosed gastritis [inflammation of the lining of the stomach] and prescribed Maxolon, an anti-nausea medication. Miss J continued to feel unwell and, on 20 July, returned to her home in Widnes. She was admitted to hospital on 22 July suffering from diabetic ketoacidosis (an excess of acid and ketones [a particular group of organic compounds] in body tissues and fluids which develops in diabetics when their condition is getting out of control, and may indicate approaching coma). She died on 31 July.

2. Mr J complained to the practice about the treatment given to his sister by the GP, and subsequently asked the North Wales Health Authority for an independent review of his complaint. The independent review was held on 6 January 1998, but Mr J remained dissatisfied.

3. The matter subject to investigation was that the independent review panel failed to follow national Directions and guidance on the reporting of independent reviews in that it did not adequately address and reach conclusions on its findings of fact and on the advice of its clinical assessors, related to the matters specified in the panel's terms of reference.

Investigation

4. The statement of complaint for the investigation was issued on 1 April 1998. The Commissioner obtained the Health Authority's comments and relevant documents were examined. One of the Commissioner's investigating staff took evidence from Mr J, the GP, members of the independent review panel (with the exception of the convener who was ill, and could not be interviewed) and the two clinical assessors who gave advice to the panel. I have not put into this report every detail investigated; but I am satisfied that no matter of significance has been overlooked. The Commissioner is conducting a separate investigation of Mr J's complaint against the GP. It is not my remit, in this report, to consider whether the panel reached correct conclusions in their consideration of the GP's actions, but to consider whether the panel acted reasonably in drawing up its report.

National legislation and guidance

5. The Secretary of State for Health, in exercise of powers conferred on him by section 17 of the National Health Service (NHS) Act 1977, issued `Directions to Health Authorities on dealing with complaints about family health service practitioners' (1996). The Directions include the following provisions in respect of the independent review procedure:

`30 The functions of the panel shall be -

`(a) to investigate the complaint; and

`(b) to make a written report to the Health Authority of the findings of its investigation.

`31(1) The functions of the assessors shall be -

`(a) to advise the panel on matters relating to the exercise of clinical judgment by the person subject to complaint; and

`(b) to make a written report to the panel of their advice.

(2) The assessors may make a joint report .... or each assessor may make a separate report.

`33(1) The report of the panel shall include -

`(b) the opinion of the panel on the complaint having regard to the findings of fact.

`(c) the reasons for the panel's opinion ....

`(e) where the panel disagrees with any matter included in the report of the

assessors, the reason for its disagreement.'

6. In March 1996 the Welsh Office issued guidance on the operation of the complaints procedure which included at paragraph 7.30:

> `Panel's final report
> The panel may find it helpful to provide the complainant and any people complained against with the opportunity to check a draft report - which may not necessarily include the final conclusions .... - for factual accuracy .... The assessors' reports should be made available in time for .... circulation with the panel's draft report.'

The Health Authority's formal response

7. On 27 April 1998, the Health Authority's **chief executive** explained in a letter to the Commissioner's office that the panel chairman had incorporated comments from the panel members and assessors on a draft of the report into a final version. Mr J wanted the report to be issued quickly, and there was no dispute about the factual evidence. The panel chairman decided, therefore, not to circulate an amended draft report to the parties to the complaint but immediately issued the final report, including the assessors' reports which had been received subsequently. The chief executive pointed out that the Health Authority had no authority to question the panel chairman's report and that it was not appropriate for the Health Authority to jeopardise the independence of the panel by seeking to influence it.

The Independent Review Panel report

8. The panel's report is dated 21 January 1998. The Terms of Reference set for the panel required it to consider (a) whether the GP, knowing Miss J was a diabetic, observed proper professional standards when he saw her on 19 July; and (b) whether he kept an accurate record of the consultation. There is no definition of `proper professional standards'. The panel's report, to which are appended the clinical assessors' reports, contains detailed findings of fact and two paragraphs headed `conclusion'. These read as follows:

> **(a)**
> **`CONCLUSION**
> *`The GP knew that [Miss J] was diabetic and had been diagnosed as MODY. He also knew that this was extremely unusual and that he only had one case, where the patient was obese, which [Miss J] was not.*
>
> *`The GP made no tests specifically geared to [Miss J's] diabetes but proceeded on the basis of suspected gastritis.*
>
> *`The GP did not make an examination in depth on 19 July 1997 ....*
>
> **(b)**
> **`CONCLUSION**
> *`The Panel found that the notes did record certain findings and the prescribed medicine. If they are a true record of the consultation then they would indicate that whilst MODY was recognised in [Miss J], no specific steps were taken by the GP to establish the precise nature of [Miss J's] diabetic condition.*
>
> *`If they do not record relevant negative findings which were drawn by the GP then we conclude that they would fall below the requirements of good practice.*
>
> *'This finding is consistent with the expert evidence of the Clinical Assessors .... '*

The clinical assessors' reports

9. The **first clinical assessor** said in her report:

> *`It is good practice to check blood sugars and/or urine of diabetics who are ill; and that*
>
> *'keeping accurate records is of prime importance in good practice. The recording of negative findings, probable diagnosis and future management should, where possible, be included'*
>
> The first assessor also observed that the `panel felt that [the GP's] record of the consultation was accurate but not very helpful. There was very little history, nor were all the symptoms or examination findings recorded'.

10. The second clinical assessor's report included nine observations about the GP's management of his patient:

> 1 `There are only scanty details of the complaints and examination in the note
>
> 2 `No record about the smelling of breath for "Ketone or Fetor (an unpleasant smell)"
>
> 3 `[The GP] failed to take and enter family history
>
> 4 `No record of advice regarding diet in view of the vomiting
>
> 5 `No record regarding enquiry of her blood test
>
> 6 `No record of advice to do the test regularly
>
> 7 `[The GP] carried out necessary examination and came to a reasonable conclusion after considering acceptable differential diagnosis
>
> 8 `Treatment provided was adequate
>
> 9 `The record keeping appears to fall below the level of good practice regarding the points mentioned above.'

Comments on the panel chairman's draft report

11. Documents sent to the Commissioner's office by the Health Authority in response to the Statement of Complaint included the convener's and lay member's written comments on a draft of the panel's report. On 15 January 1998, the Health Authority's assistant board secretary (the secretary) conveyed these comments in a letter to the panel chairman as follows:

`I have received the following comments on the Draft Report.

'[The convener] - Agreed, except with final conclusion. This seems to end suddenly!

'I [the secretary] said .... that you [the panel chairman] had not completed the conclusion until you had the Assessors' Report to hand.

'[The lay member] .... felt that the report ended rather abruptly thus appearing damning of [the GP]. Again, I [the secretary] explained that you were awaiting the Assessors' Report before completing.'

The secretary also conveyed in her letter minor, detailed, additions to the text of the draft report which were incorporated in the final version.

12. On 17 January, the convener commented further on the draft report. In a letter to the Health Authority, which was forwarded to the panel chairman, she said:

`We have not concluded whether or not [the GP] observed proper professional standards on the 19th [July 1997] .... '

13. The secretary also wrote to Mr J on 22 January 1998, to let him know that the final report of the panel had been passed to the Health Authority chief executive for circulation. The secretary said:

` .... having compiled the report, received the Assessors' reports and discussed the content of each with the Panel Members, he [the panel chairman] has decided not to circulate a draft for comment, but to issue the Final Report immediately. This is in accordance with the Guidance, which does not require the chairman to circulate a draft report'.

14. The secretary added that the report would be sent to Mr J within the next five working days. On the same day Mr J wrote to the Health Authority and asked for the report to be released immediately. On 23 January, the chief executive sent a copy of the report to Mr J who commented the same day as follows:

`Having very carefully read the report I am sorry to say that I find the report and, specifically, the findings, worded in such a manner as they could quite literally mean all things to all men.

`I am assuming by the content of the report that the panel found the care offered to [Miss J] to be of an unacceptable standard, however this is somewhat confused given the comments of one of the clinical assessors .... '

Mr J's evidence

15. When interviewed, Mr J told the Commissioner's investigating officer that the panel's report was ambiguous: it was not clear whether they were criticising the GP or exonerating him. He also said that the clinical assessors' reports reached different conclusions (see paragraphs 9 and 10).

Evidence of the panel chairman and members

16. The **panel chairman** told the Commissioner's investigating officer that he had compiled the panel's report and that copies had been sent to the Health Authority, the panel members and the clinical assessors. Before the hearing began he had decided that the panel would need to take the clinical assessors' advice as to what could reasonably have been expected of the GP in the circumstances in which he saw Miss J on 19 July 1997. The clinical assessors' opinion had been that the same standards of care should be expected from a consultation in a holiday surgery as in a normal practice surgery. Following the panel hearing the members discussed what their preliminary conclusions should be. At that stage they did not have the assessors' reports. The members were in agreement that the GP had not examined Miss J for either blood sugar or ketones; but that it was for the clinical assessors to say whether that had been reasonable. The first clinical assessor had told the chairman that she and the second assessor could not agree: but it was not clear to the chairman why that was so. The chairman surmised that the assessors were operating independently of one another, and considered that with hindsight he should have commissioned a joint report.

17. When the chairman received the assessors' reports he thought they were 'a bit thin' but believed that they confirmed the panel's views as expressed in the draft report. He was aware that the assessors had reached differing conclusions. He thought they were irreconcilable but not inconsistent with the panel's draft report, which the assessors had seen. With the benefit of hindsight the chairman believed that he should have followed up the detail of the assessors' advice. The panel had not felt able to reach a conclusion as to whether the GP had observed proper professional standards. The members felt that it would have been good practice for the GP to have tested Miss J's blood and urine, knowing that she was diabetic, but that it was not unreasonable for

him not to have done so in the circumstances. The chairman felt that the panel's report had been a 'qualified criticism' of the GP. He said, when interviewed, that he felt the report was 'as damning as it could be in the circumstances'. It was difficult, like 'walking a tightrope', between the need to be fair to the GP, in view of Mr J's anger against him, whilst recognising the family's grief.

18. The chairman added that since this case, he had tried to reach conclusions which were directly geared to the Terms of Reference and had tried to get the convener to sharpen up Terms of Reference. He now also tried to persuade the clinical assessors to produce a joint report where possible, or if not, if their views do not coincide, to explain why in the panel report. In this case, the panel had tried to produce a conclusion which encompassed the conclusions of both clinical assessors who had not agreed.

19. The panel's **lay member** told the Commissioner's investigating officer that she thought the assessors' reports had been clear, brief and to the point. She did not believe that they had reached different conclusions. She did not see the assessors' reports as in conflict because they related to the standard of care that could be expected in the circumstances of the case - a consultation in a holiday camp surgery rather than in 'a standard general practitioner surgery'. The lay member said that the first clinical assessor had been of the view that it would have been good practice to test blood and urine; the second clinical assessor advised that, in the circumstances, it was reasonable for the GP not to have done so. The lay member's own view was that it would have been good practice for the GP to have tested Miss J's urine; but she did not think that in the circumstances in which the GP had been practising, he had been irresponsible. She said it had been difficult to achieve a balance between the family's 'extreme grief' and the need to be fair to the GP in the knowledge of Mr J's 'extreme anger'.

The clinical assessors' evidence

20. The **first clinical assessor** said, when interviewed by the Commissioner's investigating officer, that she and the second assessor had been in broad agreement. She had not stated her own conclusions boldly in her report because she understood that the assessors' role was to give advice on what a reasonable doctor would have done in a particular circumstance; but not on whether the doctor had erred in the particular case. That was for the panel to judge. She said that her role was to describe good and poor practice, not to be judgmental. When she received the panel's draft report she telephoned the Health Authority and said that she was `not unhappy' with any aspects of it. She thought that the GP had observed proper professional standards and that his account of his consultation was that of a reasonable GP. However, he did fall short by failing to recognise that Miss J had a potentially serious condition. He had not given sufficient consideration to the fact that she was diabetic. Standards for the treatment of diabetic patients were different to those which applied to the treatment of illness in other people.

21. The **second assessor** said, when interviewed, that he believed his role to be to provide independent advice, not necessarily to 'reach a consensus'. He believed that the first six points in his report (see paragraph 10) were 'statements of fact with negative connotations', and related to his conclusions about the GP's record keeping (that it appeared to fall below the level of good practice). He thought that there were areas where the GP could have done better. He said that after he had considered the evidence the GP gave at the hearing and the information provided by Mr J (including the records of two GPs who had seen Miss J after the 19 July consultation) he had concluded that the GP had carried out the necessary examination, considered differential diagnoses and given reasonable treatment. The GP's account of events was supported by the records of the two other GPs who saw Miss J on her return home and who had similarly diagnosed gastritis and prescribed similar treatment.

Findings

22. Independent review panels are required in their reports to provide the parties to a complaint with an opinion, with reasons, having regard to findings of fact and taking account of the clinical assessors' views on any clinical issues involved. The opinion expressed in the report must be that of the panel. In this case, the panel's Terms of Reference as agreed with the complainant, were to consider whether the GP had 'observed proper professional standards' in the care of Miss J and whether his records were an accurate reflection of his consultation with her on 19 July 1997. It is not the purpose of this report to reach conclusions on these matters, but to consider whether the panel did so. I have concluded that the panel did not do so in any meaningful sense. The two paragraphs in the panel's report headed 'Conclusion' (paragraph 8) are, for the most part, findings of fact as to what the GP did and did not do, and what he did and did not record. I concede that the second could be read as critical of his record keeping, although the criticism is expressed in hypothetical terms. However, the panel failed to express an opinion on the adequacy of the care he gave to Miss J. That fact is borne out by the convener's statement (paragraph 12) that the panel had not concluded 'whether or not the GP observed proper professional standards ....'.

23. Mr J complained that the panel's report was

ambiguous and could be read as 'all things to all men'. I agree. At interview the panel chairman said that compiling the report had been like 'walking a tightrope' between the need to be fair to the GP whilst recognising the complainant's anger and the family's grief. I recognise the need to be fair to all parties to a complaint; but this should not prevent a panel from expressing an opinion on its findings of fact. The chairman said that he believed the panel's report was as damning as it could be in the circumstances. Mr J on the other hand was left with the understandable feeling that the panel had failed to decide one way or the other whether the GP had given his sister a reasonable standard of care. The ambiguities apparent within the panel and assessors' reports also emerged in the evidence the panel members and assessors gave to this investigation.

24. There will be occasions when an independent review reveals a conflict of evidence which a panel cannot resolve, even on the balance of probability, without being unfair to one of the parties. If this happens a panel should explain why it is unable to reach a conclusion. I do not believe that was the case here. Neither do I believe that the differences of view expressed by the clinical assessors were so great as to prevent the panel forming a view on the GP's actions. I conclude that the panel failed to reach a conclusion on the standard of care the GP gave to his patient and failed to explain why. Mr J was left with the belief that this stage of the complaints procedure had failed him. The GP was given no clear statement (save in the area of record keeping) as to whether he had acted reasonably and, if not, of how he might improve his practice. I uphold this complaint.

25. I have considered whether the deficiencies in the panel's report are sufficient to consider it a nullity and, if so, the recommendation I should make. The Directions require a panel to provide an opinion, with reasons, on its findings of fact. In this case the panel failed to do so for at least one - important - part of its Terms of Reference. To that extent it did not, in my view, complete its work. However, I have decided not to invite the Health Authority to ask this panel or a fresh one to reconsider Mr J's complaint. The Commissioner is conducting an investigation of the GP's actions and this should satisfy the complainant's desire for an independent investigation of his concerns.

26. I note that lessons have been learned from this case about the conduct of panels and the process for obtaining and handling independent clinical advice. The Commissioner accepts the comment by the Health Authority chief executive that there is limited scope for a health authority to influence the conduct of independent reviews. The complaint which I have upheld is against the Health Authority as the independent review panel was formally a committee of that Authority. However, the Commissioner is required by statute to copy his reports to the Secretary of State for Wales and I look to the Welsh Office to take steps to ensure that lessons from this report are learned for future independent review panels, whether in this health authority or others in the Principality.

27. I am concerned about some other aspects of the panel's construction and handling of its report. The guidance and Directions governing the operation of the complaints procedure do not, it is true, require a panel chairman to circulate a report in draft to the parties to a complaint. They do, however, state that the assessors' reports should be made available in time for circulation with the draft report. If, as in this case, the draft report purports to contain conclusions, it is only reasonable to wait for the assessors' report(s) before arriving at those conclusions. That was not done on this occasion.

Conclusions

28. This report considers one aspect of a compendium of complaints from Mr J about the care his sister was given and how his complaints were handled. I have set out my findings in paragraphs 22 to 27 on his complaints about the report of the review panel established by the North Wales Health Authority. The Authority has asked me to convey - as I do through my report - its apology to Mr J for the shortcomings I have identified.

March 1999

NHS Independent Review Panel

Independent Review - Mr J Regarding the Late Miss J

DATE OF PANEL - 6 JANUARY 1998

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Terms of Reference

To investigate the facts and reach conclusions on the following:

1 Whether Dr B, knowing that the late Miss J was a diabetic, observed proper professional standards in dealing with her on the 19 July 1997.

2 Whether he kept an accurate record of the consultation on the 19 July 1997.

NHS Independent Review Panel - Mr J Re the Late Miss J

Terms of Reference

1. The Panel was convened on 18 December 1997, following formal complaint by letter from Mr J, brother of the late Miss J, dated 13 November 1997. The Panel was convened, after consultation with the lay Chairman.

2. The Terms of Reference had been agreed with Mr J and were:

To investigate the facts and reach conclusions on the following:

1. Whether Dr B, knowing that the late Miss J was a diabetic, observed proper professional standards in dealing with her on 19 July 1997

2. Whether he kept an accurate record of the consultation on 19 July 1997

Membership

3. Panel members were:
Chairman
Convener
Independent Review Panel Member

Clinical Assessors were:
GP 1
GP2

Evidence

4. Written evidence, consisting of correspondence and Dr B's clinical notes, totalling 12 pages, was made available to all members, assessors and parties before the hearing, which took place at H M Stanley Hospital, St Asaph, Denbighshire at 9.30am on Tuesday, 6 January 1998.

Evidence in person was heard from
Mr J
Fiancé of the late Sarah Jane
Dr B - General Practitioner
Dr G - as friend to Dr B representing the GMC

5. Prior to the hearing, Mr J had made available to Panel Members a comprehensive bundle setting out the history of the case, totalling 39 pages, with appendices of diabetic treatment and protocol, together with extracts from medical journals explaining current medical opinion on the subject. Much of this material was not germane to the Panel's Terms of Reference, but it provided useful background information and enabled the Panel to consider the Terms of Reference within a whole picture.

6. The evidence given by Mr J was supported by a 20 page written statement made available to the Panel at the hearing.

Agreed Facts

7. Miss J died tragically in her 21st year on 31 July 1997 when life support was terminated following collapse on 23 July 1997. Cause of death was certified as "acute cerebral oedema" and "diabetic ketoacidosis".

8. On 12 July 1996 Miss J had been diagnosed as MODY i.e. Mature Onset Diabetes of the Young. At this time Miss J was aged 19 years and four months. Such condition would not require administration of insulin and would thus be described as NIDDM, or type two diabetic, as opposed to IDDM or type one diabetic.

9. The Panel received evidence, confirmed by both Clinical Assessors and by Dr B, that MODY is an extremely rare condition. Both Clinical Assessors have been in practice for many years but neither had come across a case. Dr B gave evidence that he had heard of it at Medical School and had one obese patient with the condition.

10. The Panel accepted as fact that it is unlikely that a young person with diabetes would be NIDDM.

11. The Panel therefore concluded that, in fact, Miss J was probably not NIDDM but that, even if she had been, her condition would require utmost care and control. This opinion is based on evidential probability and on the tragic outcome of Miss J's case. The circumstances of the diagnosis as MODY are beyond the Panel's Terms of Reference.

Holiday Centre

12. Miss J arrived at the Holiday Centre, accompanied by her Fiancé, on Friday, 18 July 1997. Records indicate that she had been feeling unwell before her journey. Her fiancé gave evidence that, during the evening and night of 18 July, Miss J was "actually sick a number of times".

13. She continued to feel unwell and attended the Surgery at the Holiday Park at 4.00pm on Saturday,

19 July, accompanied by her fiancé. There were other people attending the Surgery - evidence indicates their number as two.

Surgery

14. The Surgery is held at the Holiday Park.

Hours are displayed prominently at the Surgery and are:

Monday - Friday	12.30pm -1.00pm
Saturday & Sunday	4.00pm -4.30pm

Nurse on duty

Monday - Friday	10.00am -4.00pm

Emergencies - contact security

15. Whilst hours appear to be minimal Dr B stated in evidence that they were adequate since most people who come on holiday were in good health. Those that were not tended to stay at home. Saturdays were particularly quiet since Saturday appears to be changeover day.

Dr B

16. Dr B is a General Practitioner having qualified at a London teaching hospital. He has been in general medical practice for some 12 years and is Senior Partner of three in his current practice. The Practice has approximately 5,000 patients and the work at the Holiday Park, where there are 1000 caravans (approx.) is undertaken during the holiday season.

Consultation on 19 July 1997

17. Miss J was seen by Dr B at between 16.15 and 16.30 hours on Saturday, 19 July 1997. On arrival at the Surgery she had been asked to complete a visitor form. The form appears to have been completed by Miss J and there is no evidence that she was actually sick during her visit to the Surgery.

18. Evidence was received from Miss J's fiancé that he attended the consultation with Miss J. Dr B was not certain about this, could not recollect it, and did not "see it as an issue". The Panel therefore accepted that the fiancé was present at the consultation.

Examination

19. The Panel found that Miss J indicated to Dr B that she was MODY. This is evidence from Dr B's notes of the consultation and he recalled the fact since it was so unusual.

20. Miss J also informed Dr B that she had been vomiting for the last two days, but Dr B indicated that she was not sick during the surgery visit.

21. Dr B gave evidence that Miss J appeared to be a healthy young woman, and discussed Miss J's testing for blood sugar with her. She indicated to him that she had not done a test. Dr B did not test specifically for diabetic control.

22. The Panel found that Dr B did not consider hyperglycaemia nor diabetic ketoacidosis. He examined Miss J for appendicitis and gastritis and formed the opinion that she was probably suffering from gastritis.

23. Accordingly he prescribed Maxolon, an anti-nausea medicine, and as is standard practice asked Miss J to return the next day if she were no better.

24. The Panel found that Dr B had no access to Miss J's Medical Records and did not make enquiry into the detail of her medical history. He did state that there was no smell of ketones on her breath, detectable during the course of his examination, but he did not specifically make this test and did not record anything in the medical notes.

25. It appears that the examination carried out by Dr B was based on his observation that she appeared to be a healthy young woman. He did not consider it necessary to arrange admittance of Miss J to hospital.

26. Miss J left the Holiday Park early on Sunday, 20 July 1997, having continued to be unwell. She was seen by her GP at 10.45am on that day.

Conclusion

27. Dr B knew that Miss J was diabetic and had been diagnosed as MODY. He also knew that this was extremely unusual and that he only had one case, where the patient was obese, which Miss J was not.

28. Dr B made no tests specifically geared to Miss J's diabetes but proceeded on the basis of suspected gastritis.

29. Dr B did not make an examination in depth on 19 July 1997.

Records

30. A copy of notes of Miss J's consultation with Dr B was made available to the Panel.

31. The NHS temporary services record appears to have been completed in a mature and firm hand by Miss J but there was a discrepancy in the spelling of her Christian name.

32. A note was also made of the name of Miss J's GP, and of his address.

33. The clinical notes indicate

(1) that Miss J had been vomiting for the last two days out of seven.

(2) that she was MODY

(3) that her abdomen had been examined and appeared normal

(4) that her bowels had been reported as open

(5) that she had been prescribed Maxalon.

34. Other notes had been made but these were not considered relevant, since they had been made after notification of Miss J's death by her brother.

35. The notes make no reference to any other findings, nor of any negative ones which would be relevant when considering problems specific to diabetes. Thus no reference is made to the absence of a smell of ketones on Miss J's breath, nor any other negative indications.

36. The form appears to have been signed and dated by Dr B.

Conclusion

37. The Panel found that the notes did record certain findings and the prescribed medicine. If they are a true record of the consultation then they would indicate that whilst MODY was recognised in Miss J, no specific steps were taken by Dr B to establish the precise nature of Miss J's diabetic condition.

38. If they do not record relevant negative findings which were drawn by Dr B then we conclude that they would fall below the requirements of good practice.

39. This finding is consistent with the expert evidence of the Clinical Assessors, whose Reports are attached verbatim.

CHAIRMAN
21 January 1998

Independent Review Regarding The Late Miss J : 6 January 1998

40. The review panel was asked to consider:-

1. Whether Dr B, knowing that Miss J was diabetic, observed proper professional standards in dealing with her on 19 July 1997.

2. Whether Dr B kept accurate records of the consultation.

41. It was very obvious that Mr J, the complainant, was still grieving and had not come to terms with the death of a dearly-loved sister. He had done a great deal of research into diabetes and the factors leading to her death. Both the quantity and quality of his research were recognised, but some of his conclusions were open to different interpretations.

The Consultation

42. Dr B's recollection of the consultation between himself and Miss J differed from the account given by Miss J's fiancé, who said that he was present during the consultation. Dr B said that Miss J had waited about 20 minutes in the waiting room without obvious discomfort. She had filled in the Temporary Resident form clearly and legibly, a factor which he considered to be an indication that she was not too distressed physically. He said she told him she was a diabetic - MODY (which is controlled by diet alone) - and that she had been vomiting off and on for 2 days. He said that he examined her abdomen. He did not notice any smell of ketones on her breath. He asked her questions about her condition. He elicited the fact that she had not tested her blood sugar recently and that she never tested her urine. He was satisfied that Miss J was only slightly unwell.

43. He felt that given his findings he treated her appropriately and he told her to make contact the next day if she became worse.

44. Her condition worsened during the night of 19 - 20 July and she felt that return home was her best option. It seemed that while Miss J was not very ill when she saw Dr B, her condition deteriorated after she left the camp.

45. It is good practice to check blood sugars and/or urine of diabetics who are ill. A simple urine test can be a guide to the seriousness of the condition and to whether other tests should be carried out.

The Record

46. The Panel felt that Dr B's record of the consultation was accurate but not very helpful. There was very little history, nor were all the symptoms or examination findings recorded.

47. Keeping accurate records is of prime importance in good practice. The recording of negative findings, probably diagnosis and future management should, where possible, be included.

Report of the Independent Assessor - GP1

The report should be read in conjunction with the Terms of Reference.

48. I carefully read what Mr. J submitted in his letter and also took into account his verbal deposition.

49. I also had the opportunity to read through the letter submitted by Dr B and carefully noted what he had to say during the interview.

50. My conclusions are as follows:

1. There are only scanty details of the presenting complaints and examination in the note.
2. No record about the smelling of breath for "Ketone or Fetor".
3. Dr. B failed to take and enter family history.
4. No record of advice regarding diet in view of the vomiting.
5. No record regarding the enquiry of her blood test.
6. No record of advice to do the test regularly.
7. Dr. B carried out necessary examination and came to a reasonable conclusion after considering acceptable differential diagnosis.
8. Treatment provided was adequate.
9. The record keeping appears to fall below the level of good practice regarding the points mentioned above.

The care provided to Ms J at Halton General Hospital

Complaint against

Halton General Hospital NHS Trust

Complaint as put by Mr J

1. The account of the complaint provided by Mr J was that in July 1996 his sister, Miss J, was diagnosed with Maturity Onset Diabetes in Youth (MODY). Her diabetes was controlled by diet. On 22 April 1997, Miss J attended the diabetic clinic at Halton General Hospital where she saw a consultant (the first consultant) and a diabetes nurse specialist (the nurse specialist). Her blood glucose reading was 10.3mmols. Her treatment was not altered. On 14 July, Miss J tested her blood glucose and recorded that it was 11. During July Miss J felt unwell and consulted three general practitioners on four occasions. On 22 July, Miss J was admitted to Halton General Hospital (the hospital) with diabetic ketoacidosis (an excess of acid and ketones in body tissues and fluids which develops in diabetics when their condition is getting out of control, and may indicate approaching coma). She appeared, initially, to respond to treatment, but at 8.00pm developed a severe headache, which recurred at 3.00am shortly before she collapsed. She had developed cerebral oedema (swelling of the brain within the skull) and lapsed into coma on 23 July. On 29 July, brain stem death was diagnosed and on 31 July, Miss J's ventilator was switched off.

2. On 18 February 1998, an independent panel review was held at the hospital to consider complaints made by Mr J about his sister's care and treatment. The panel subsequently issued a report, which included a statement that the panel considered that Miss J had had 'difficulty in coming to terms with the diagnosis of diabetes' and suggested that she had suffered a 'denial reaction'. Mr J remains dissatisfied and complains that staff at the hospital mismanaged his sister's care and that the panel was wrong to assert that his sister was in denial of her illness.

3. Mr J believes that his sister's death could have been avoided and that it was caused by a combination of misdiagnosis; inadequate education about management of diabetes; poor monitoring of her condition in the Trust's diabetes clinic; the failure of general practitioners to check Miss J's blood sugar when she reported symptoms including vomiting, which he contends indicated the onset of diabetic ketoacidosis (and should, of themselves have triggered testing even if diabetic ketoacidosis had not been suspected); and mismanagement of diabetic ketoacidosis during her admission to hospital, including over-administration of fluids, which he believes caused cerebral oedema and thereby her death.

4. The matters investigated were that:

   (a) the care and treatment provided to Miss J by Halton General Hospital NHS Trust was inadequate; and

   (b) that the report of the independent review inappropriately included a statement that Miss J was in denial of her diabetes.

Investigation

5. The statement of complaint for the investigation was issued on 8 June 1999. Comments were obtained from Halton General Hospital NHS Trust; and relevant documents, including Miss J's clinical and nursing records, were examined. My investigator took evidence from Mr J, Miss J's parents and Trust staff. Clinical advice was provided by five external professional assessors; and their report is at Appendix A. I have not included in this report every detail investigated, but I am satisfied that no matter of significance has been overlooked. This was a detailed and complex investigation; and, for reasons of brevity, the evidence contained within this report is a summary of that considered most pertinent to the case. In addition, my Office has previously investigated two other complaints from Mr J, relating to his sister's diabetic care by a general practitioner and the handling of his complaint by the relevant health authority. The reports of these investigations have been published (W.138/97-98), (W.125/97-98). The actions of the two other general practitioners concerned were considered and criticised by independent review under the provisions of the NHS complaints procedure. I have included information about events which were external to Miss J's involvement with the Trust to set matters in context; and to facilitate a clearer view of the events leading to Miss J's death. I emphasise, however, that in making my findings, I have considered the actions of the Trust staff on the basis of information to which they had access. A glossary of terms is at Appendix B.

(a) The care and treatment provided to Miss J by Halton General Hospital NHS Trust was inadequate

6. I set out the evidence below in chronological sequence.

Background information

7. The notes of Miss J's GP record that on 26 February

1996, Miss J consulted her GP, complaining of feeling faint about one hour after her mid-day meal. Her grandmother had tested her urine which showed glycosuria. The GP diagnosed asymptomatic reactive hypoglycaemia. On 13 March, the GP explained the diagnosis to Miss J and arranged a referral to a consultant endocrinologist (the first consultant). On 29 March, the notes of Miss J's GP record that diabetic diet was discussed, and that she was referred to a chiropodist and advised to see an optician in six months time. At this stage, her diabetes was being monitored by the practice.

Diabetic clinic

8. Miss J's clinical and nursing records show that on 12 July 1996, Miss J was seen by the first consultant at the Trust's diabetes clinic. He entered a diagnosis of MODY in her notes. He wrote to her GP and told him that she 'is a most interesting MODY' and he also thought her thyroid gland was enlarged; that she should manage well on diet; and that he would review her notes with the nurse specialist in two months and see her in the young persons' diabetes clinic in 4 months. She was seen separately by the nurse specialist that day, who recorded that Miss J was 'diet only'; that they had had a 'general chat about diabetes'; that she had taught Miss J how to test her blood; and that 'info.' had been given. Miss J then continued to be monitored at intervals by the nurse specialist, and the first consultant at the young persons diabetes clinic

Miss J's blood result diary

9. Miss J's record card shows that she tested her blood at approximately 3-5 day intervals. There are some extended periods during which she did not record results in her diary, and which appear according to evidence supplied by Mr J to coincide with holiday periods. Her results ranged between 4 and 7. On 26 July 1996, she recorded 9mmols which was noted by the nurse in her records as 'odd one at 9mmols'. Miss J also recorded a reading of 11mmols on 6 September 1996 and ceased testing for a period. The reading was highlighted by a circle, but was otherwise not remarked upon.

Mr J's evidence

10. Mr J contends that the first consultant should not have reached an initial diagnosis of MODY and that his sister did not fit the criteria for such a diagnosis. Mr J believes that the first consultant should have been more cautious and considered whether Miss J might have been a slow onset type 1 - a much more common form of diabetes in the young. If the first consultant had reached a correct diagnosis Miss J would have received education relating to type 1 diabetes; and would have been taught to test her urine for ketones and about the signs to watch for of developing diabetic ketoacidosis. He thought the nurse specialist should have questioned the diagnosis of MODY and taken steps to ensure that she was sufficiently well-informed about the condition to care for his sister appropriately. He also complains that neither the first consultant, nor the nurse specialist gave his sister appropriate education; and that they failed to tell her what to do in the event of illness, what action to take in the event of hyperglycaemia, and how to recognise the symptoms of diabetic ketoacidosis. Mr J maintains that Miss J's blood glucose and HbA1c measurements during the period of monitoring at the clinic clearly indicated declining diabetic control and that action should have been taken to alter his sister's management.

Evidence of Miss J's parents

11. Miss J's mother explained that her daughter saw the first consultant on her own. She then saw the nurse specialist who told her that she need test her blood only every 4-5 days. The nurse specialist taught her how to use a diabetic pen (for testing her blood sugar) and gave her a diary to record the results. She also told her to have her eyes and feet checked regularly, and that she would be referred to a dietician. The first consultant had said to Miss J that 'if she stuck by him and did what he said she would never need insulin', which pleased her. On 22 August 1996, the nurse specialist came to see Miss J at home (she lived with her parents). She asked how she was, and she said she was fine. She again said that Miss J should test every 4-5 days and, when she asked what she should do while on holiday for two weeks, the nurse specialist told her that she should test before she went and again when she returned. Conversation then turned to general matters. Her daughter was not given any literature by the nurse specialist other than a British Diabetic Association membership form, and a price list. Miss J's diabetes clinic card was shown to the investigator. Miss J had written 'I have MODY diet controlled diabetes'.

Evidence of Trust staff

12. The **first consultant** is a consultant physician in diabetes, endocrinology, and general medicine. He ran two diabetes clinics: an adult clinic and a young persons clinic where he saw young patients (between the ages of 18 and 30) frequently. Miss J was seen for her first appointment in the main (adult) diabetes clinic. The first consultant explained what diabetes was. She had been quite worried, and thought she might have type 1 diabetes. The first consultant explained the difference between type 1 and type 2 diabetes, and told her that he did not think she had type 1 but that he would keep 'a close eye' on her. He thought type 1 was a possibility but, based on the history she had given him and his clinical findings, thought she actually had MODY. Miss J told him that her mother was diabetic and that her grandfather had also been diabetic and had used insulin. The first consultant did not know whether he was type 2 insulin treated or not. The first consultant concluded, therefore, that Miss J was from a family with a

diabetic history over three generations; that her onset was at under 25 years of age; and that she was symptomatic, but had not lost weight. The first consultant acknowledged that he had written to Miss J's GP with a diagnosis of MODY, but stressed that he had referred her to the young persons clinic (usually attended by people with type 1 diabetes) where she could be monitored more closely. He saw Miss J four times over the next 9 months. He also explained to her what type of problems she might experience as a result of her diabetes. The consultant was sure that Miss J understood the difference between type 1 and type 2 diabetes and he explained to her the risk of hyperglycaemia. Her HbA1c was under 7.5 at every visit; at the last visit it was 7.3. The first consultant had referred Miss J to the nurse specialist. The guidelines recommended by the British Diabetic Association had been followed - that non-insulin patients should not routinely be taught ketone testing. Miss J was told to contact the clinic if her blood sugar exceeded a reading of 9. The first consultant recognised that there was an increased risk of decompensation with diabetes and autoimmune thyroid disease.

13. The **nurse specialist** said, when interviewed, that she was employed as a specialist nurse and had held this post for just under two years when she saw Miss J. She was responsible for the young persons clinic. She usually sat in on consultations with patients. However, as Miss J was seen first at the adult clinic she had not been privy to the conversation with the first consultant. Miss J saw the first consultant and then came to see her. The nurse specialist said that her understanding at the time was that MODY would be managed in the same way as for a type 2 diabetic - ie taught to be aware of normal blood sugar levels, about monitoring and the need to be aware of changes. She would not have told Miss J about diabetic ketoacidosis as she would not be using insulin in the short term. She told the investigator that when teaching a patient such as Miss J to test their blood she would tell them what the normal range was; that she would expect their fasting and pre-meal blood sugars to be between 4 and 7; and that random blood sugar should not exceed 9. She would have told Miss J to test 2-3 times a week (Note: this figure varies in the evidence between 2-3, 3-4, 4-5). If patients recorded a high reading, 11 for example, they would be advised to test again the next day if they felt well, or later that day if they felt unwell. They would always be told to consider how they were feeling. She would explain that the reason for testing was to avoid hyperglycaemia. She would not be concerned about one high reading in isolation, but would have been looking for a general change in the pattern of results when reviewing Miss J's self-tested blood results. (Note: it is not possible from the documentary evidence to determine precisely what was or was not said to Miss J in this regard.)

14. The nurse specialist would normally give out two forms of literature: a Balance (diabetes information) magazine and a type 1 or type 2 diabetes leaflet as appropriate; and she thought she had given them to Miss J. The diabetes record card was a 'stand alone' document containing personal details and a record of each visit. Record cards were filled out by the nurse specialist and kept in the clinic office. There was no care plan system at that time. Doctors made entries in the case notes and patients kept diaries to record their blood testing results. The nurse specialist accepted that her standard of documentation had not then been good enough; she had since made improvements. She accepted that if she had at least written 'sick day rules explained' instead of simply 'info. given' or 'all well' she might not now be facing a complaint as she would have been able to draw on documentary evidence as confirmation of the advice which she believed she gave to Miss J.

15. The clinic also now operates a revised educational procedure. There is a mini check list for type 1 young persons which they tick to indicate they have been given an education update. Those with type 2 diabetes are taught about targets for control; their understanding of HbA1c results is checked; and their education review is tailored to their individual needs. Young persons are also subject to an annual education review which is signed off by both patient and nurse. Records are now more detailed and clear. The nurse specialist agreed that she would have told Miss J that she need test only at the beginning and end of a holiday; but she would have added the proviso that she should take her equipment with her and test more frequently if she felt unwell. Miss J was last seen in the clinic on 22 April 1997.

Events in the week before admission

16. On 14 July 1997, Miss J recorded a higher than average blood sugar reading in her record book (11mmol); and on 16 July she saw her GP, complaining of muscle pain and lethargy. The GP recorded that she had limb girdle weakness in her shoulders and thighs, and that her thyroid hormone level was 'borderline'. The GP passed this information to the consultant. (Note: the GP's notes reveal no more than that he contacted the first consultant following this consultation.) The GP did not test Miss J's glucose levels or urine and there is no mention of diabetes in his record of the consultation. On 17 July, Miss J tried to test her blood on two occasions, but was unable to read the result. Her niece, who was present, also tried, at Miss J's request. The niece thought that the reading was between 7 and 9, but could not be certain. Miss J made no entry in her book. On 18 July, Miss J travelled with her fiancé, his cousin and his cousin's wife, to a holiday camp intending to celebrate the cousin's 21st birthday.

17. During the journey Miss J began to feel unwell. The following day she saw a GP at the holiday camp complaining of stomach pain and that she had been

vomiting for two days. She told the GP that she was a diet controlled MODY patient, and that she had not tested her blood glucose level. The GP did not test it or her urine: he diagnosed gastritis, and prescribed an anti-nausea medication.

On 20 July, Miss J returned home, still feeling unwell, and was visited by a locum GP who noted abdominal tenderness and vomiting 'since last Friday'; that she was a diet controlled diabetic; and that she was not dehydrated. The locum GP also diagnosed gastritis. He did not test her blood sugar or her urine. On 21 July, Miss J was seen at home by her own GP, who recorded that she had been vomiting for 3 days, was being made sick by the anti-nausea medication she had been given, was passing urine normally and was not dehydrated and that her random blood sugar level was around 7. (Note: The GP has said that Miss J's mother told him this, though Miss J's mother denies that she did.) Miss J's GP also diagnosed gastritis and did not test her blood or urine. On the morning of 22 July, Miss J's family called her GP, who recorded that she had been delirious all night and that her 'parents were unable to check her blood sugar'. The GP arranged Miss J's immediate admission to hospital by ambulance.

Hospital admission

Summary of clinical and nursing notes

18. Miss J's notes contain detailed entries specifying tests carried out and the results. My advisers have concluded that the records show that she was diagnosed as having diabetic ketoacidosis; that her sodium level was unusually low on admission to hospital, (hyponatraemia); that the acidosis had not been brought under control; and that her fluid balance was negative, rather than positive. My internal professional adviser has concluded that, judged from the composite evidence of fluid intake, urinary output, likely initial volume deficit, insensible loss from skin and lungs, plasma creatinine and urea concentrations, the absence of leg or back oedema (swelling) and the first CVP measurement (on 23 July), the initial fluid deficit was corrected and there was no evidence of material fluid overload by the time the intravenous fluid intake was reduced on 24 July. All the evidence taken together, accepting inaccuracies in charting, indicates that by the end of 24 July her total fluid volume was effectively in balance. The notes record three episodes of headache at 8.00pm on 22 July and at 2.00am and 3.00am on 23 July. The post mortem report listed the cause of Miss J's death as 1) cerebral oedema, and 2) diabetic ketoacidosis. In view of the volume of technical information, I have included only key points from the notes, but they have been considered in their entirety by my external clinical advisers in conjunction with comments made by Mr J. The notes include the following information:

22 July 1997

At 1.30pm hrs the first consultant wrote the following advice noting high potassium and acidosis: '.... Check potassium again, if high again and pH still 7.1 or less suggest small bolus [bicarbonate] 50mls over fi hr, this will reduce potassium' .... Following later discussion with the first consultant, the registrar did not administer bicarbonate.

At 3.45pm the first consultant returned. His assessment was that Miss J was better, noting that her potassium and glucose had improved but that she was still acidotic. He wrote, '.... Still vomiting but better .... pH still 7.1 may need small amount of [bicarbonate] 50mls of 8.4% [sodium bicarbonate] over fihr will probably need to give a small amount of [potassium chloride] at same time to ensure potassium doesn't drop significantly'

At 6.00pm the first consultant reviewed Miss J again and concluded that she was 'better still', nevertheless he suggested switching the intravenous infusion to 10% dextrose and giving a bolus of bicarbonate to correct the acidosis.

At approximately 8.00pm Miss J suffered a headache and became increasingly agitated. Physical examination revealed no objective neurological signs: the SHO noted that her metabolic status was not improving. Following a review of the notes, the SHO in her written statement says, '.... unsure which advice in notes to follow, therefore decided to ask both the [second] Registrar as senior, [the second] Consultant physician as knew case and [the first consultant] as knew case but not on call ....' The second registrar advised giving intravenous bicarbonate 100mls of 8.4%. The second consultant advised the SHO to contact the first consultant for his advice before administering the bicarbonate. The possibility of cerebral oedema was not suspected as a possible cause of headache and agitation.

At 8.55pm the SHO began giving a small amount of 10% dextrose pending the first consultant's advice. The SHO then requested the locum anaesthetic SHO to place an arterial line: this was achieved after three attempts.

At approximately 9.40pm the SHO spoke with the first consultant on the telephone. He advised her to give 50mls of intravenous sodium bicarbonate and supplementary potassium and to discontinue the 10% dextrose. He also gave further instructions regarding a revised insulin sliding scale and how and when to use 10% dextrose if the acidosis should continue.

By 11.30pm Miss J appeared settled: her pH was 7.14.

At midnight, following the bicarbonate, the pH had risen to 7.25.

23 July 1997

At 3.30am the SHO was called urgently to ITU, where she was told that Miss J's condition had suddenly deteriorated. The SHO noted a reduced consciousness level, reduced respiratory rate, and hypotension (low blood pressure) with tachycardia (rapid heart rate). Staff reported that Miss J had been complaining of increased headache since approximately 2.00am.

A CT scan of Miss J's brain was performed approximately four and a half hours after she had become comatose, requiring ventilation. The consultant radiologist's report says, 'Generally the brain appears "tight" and I suspect a degree of cerebral oedema. There is no convincing evidence of a subarachnoid haemorrhage. No mass lesion is demonstrated'.

During the afternoon of 23.7.97 a consultant neurologist reviewed matters and wrote, '.... the CT does not show any focal lesion, haemorrhage etc. There may be some mild symmetrical swelling of the cerebral hemispheres, but in someone of her age the scan may well be normal. In particular I note that the lateral ventricles are easily visible. She has been exceedingly unwell from the metabolic/electrolyte/acid-base viewpoints, with shifts in solutes and fluids. I think this may have played a role, and certainly myelinolysis may sometimes be more extensive than just the pons ....'.

Thereafter Miss J never regained consciousness, requiring ventilation until her death on 31.7.97.

All possible reasons for her comatose state were sought; but no specific cause was found. Empirical treatment for any reversible condition was given. Cerebral oedema was considered to be the most likely explanation for her sudden deterioration.

Mr J's evidence

19. Mr J contends that staff failed to manage his sister's acidosis adequately; over-infused fluids to a significant extent, failed to keep an accurate fluid chart; did not insert a central venous pressure line (CVP); did not observe his sister's neurological functioning following her headache at 8.00pm on 22 July; and, most significantly in his view, were unaware of the risk of cerebral oedema in relation to diabetic ketoacidosis and did not initiate treatment with mannitol which might have averted the onset of cerebral oedema. He was certain that his sister's headache at 8.00pm, in which she clutched the back of her head, (occipital region) indicated the onset of cerebral oedema. He pointed out that the first consultant's written statement described the same symptoms at 3.00am on 23 July and that the earlier occurrence must, therefore, have been the start. If treatment had commenced at that time Mr J believes that his sister's death could have been prevented.

Evidence from Miss J's parents.

20. Miss J was admitted to the hospital's A&E department on 22 July 1997 - her speech was slurred. A doctor [the SHO] put up a drip and a nurse asked how far she wanted it opened. The doctor replied, 'fully because she needs this quickly'. The doctor [SHO] told Miss J's parents that she was very poorly; but that they were 'getting her stabilised'. Miss J's mother told the doctor [SHO] that the GP had asked her to test her daughter's blood just before the ambulance had arrived to take her to hospital, but that Miss J had not wanted her to. At the hospital a doctor told them that Miss J was to be transferred to intensive care overnight to stabilise her condition. Miss J was anxious about this; but a nurse reassured her and said that she was simply going to intensive care overnight as a precaution and would go to an ordinary ward in the morning. Staff wanted to insert a catheter; but Miss J refused to let them. She did not seem to be herself. At about 7.45pm Miss J began to scream 'unmercifully'. She held the back of her head and kicked off her bedding. A staff nurse (the first staff nurse) ran up and asked Miss J what was the matter. Miss J's mother apologised on her behalf, and explained that her daughter was not normally like that. The family were ushered out but could still hear Miss J screaming. Then it suddenly went quiet. They went back in and believed Miss J to have been sedated. She appeared to be asleep, but her face was sweaty and her breathing shallow. Another nurse (the second staff nurse) joined them. The first staff nurse told the family to go home, and that they would 'find a different person in the morning'.

21. At 2.55am on 23 July, Miss J's mother awoke suddenly with a premonition that something was wrong. She telephoned the hospital and was told that something had gone badly wrong, and that they would call her back when the doctor had seen Miss J. About 5.30am Miss J's mother spoke to a doctor (the second consultant) who told her that Miss J had collapsed and had been put on a ventilator. They later met the first consultant at the hospital, who said that he did not think Miss J's collapse was related to her diabetes. He told them the situation was very grave. He also asked why they had not got her to hospital earlier. A nurse also talked to them and told them about diabetic ketoacidosis. They had never heard anything about it before. If they had known it was a risk, they would have been on their guard. (Note: the family was told later that Miss J's brain had swelled a little.)

Evidence of Trust staff

Medical staff

22. The **senior house officer** (SHO) who first saw Miss J on admission, said when interviewed that she had been employed at the Trust as a locum, and that 22 July had been her second day at the Trust. She had been responsible for one ward, which was for acute admissions through the minor injuries unit and for GP

referrals. Responsibility was split after 5.30pm with the medical registrar. The medical staff on duty at the time of Miss J's admission were: consultant on call (the second consultant); the SHO, a house officer; and a staff grade doctor, acting as registrar on duty from 9.00am - 5.00pm (the first registrar), who was replaced from 5.30pm by a locum medical registrar (the second registrar). The SHO had a first day induction to duty. A ward sister took her round the ward and explained the routine. The first registrar explained the SHO's responsibilities. The SHO could not recall having been shown treatment protocols. There was no central figure co-ordinating her induction to duty; and no written package of information was given to her. (Note: Despite these reservations my advisers have complimented the SHO on the exemplary care she gave at this time.)

23. When Miss J was admitted, the SHO saw her and realised that she was very unwell. She had dealt with diabetic ketoacidosis before and was familiar with the standard treatment; and so she commenced investigations and treatment and contacted senior staff. Miss J was more unwell than any patient with diabetic ketoacidosis the SHO had seen before. (Note: personal notes written by the SHO on 4 August 1997 recorded that Miss J was 'intermittently hysterical, screaming "I want a drink"'. She also recorded that Miss J's GP had told the parents that she was not dehydrated, to which the SHO had replied, 'well, she is now'.) The first registrar arrived and carried out her own assessment of the patient; she confirmed the SHO's diagnosis and management. The hospital's own diabetic ketoacidosis treatment protocol was not drawn to the SHO's attention until 11.00pm, when the charge nurse in intensive care did so. The first registrar confirmed her diagnosis, decided to admit Miss J to intensive care overnight, and took over her care until 5.00pm that evening.

24. At 8.00pm the SHO was bleeped by the nurse in charge and was asked to review Miss J urgently because she was very agitated and complaining of headache. She went to see her. Miss J was very panicky and crying, "I'm having a brain haemorrhage, please do something, please help me". The SHO had observed previously that she was a nervous patient and that staff had found it difficult to reassure her. There was no fluctuation in her level of consciousness. The SHO thought Miss J's headache was due to dehydration and gave her Calpol (liquid paracetamol) as she did not like swallowing tablets. That seemed to settle her down. The SHO checked Miss J again at 9.00pm and found that the Calpol seemed to have worked.

25. The SHO said that she was 'vaguely aware' of cerebral oedema from her paediatric training three years before; but it was not mentioned to her by any of the senior doctors or nurses. She contacted the first consultant at 9.30pm who gave her a management plan. She understood that the second consultant, in liaison with the first consultant, was in charge of Miss J's care. The SHO stayed in ITU until 1.30am. She was not informed of any resumption of headache until 3.30am when she was bleeped and told that Miss J had collapsed.

26. The **first registrar** said that when she saw Miss J in the minor injuries unit she was conscious and talking. A drip had been inserted; and her heart rate and blood pressure were stable. Bloods samples had been sent to the laboratory. She took another sample to test Miss J's electrolytes. She saw and endorsed the SHO's care plan and arranged for Miss J's admission to ITU. She did not refer to the written protocol but to her own knowledge. She attempted to insert a CVP line by the subclavian route; but could not get a vein. Miss J was 'very fed up', her vital signs were satisfactory, and urine output was good. The first registrar did not think Miss J would accept another attempt being made at that time. If she had thought the procedure essential she would have called an anaesthetist. The consultants arrived just before the abortive attempt at insertion. They reviewed the care plan, made no changes to it, and instructed the first registrar to carry on. She spoke to the SHO before she went off duty, but not to the second consultant. She viewed the first consultant as the consultant in charge of Miss J's care at this time. The first registrar was worried about Miss J's condition because her pH had stayed at 7.1; and because she had passed as much fluid as she had been given and attempts were being made to rehydrate her. The first registrar was aware of the risk of cerebral oedema as she had worked previously for a consultant who had an adult patient who had developed diabetic ketoacidosis; but it was not discussed in this case and there was no reason to suspect it might be a factor. The use of Mannitol was not considered.

27. The **second consultant** said that he was a consultant physician with a special interest in respiratory medicine. He confirmed that the on call consultant arrangements entailed 24 hour shifts. In Miss J's case, he was the on call consultant that day and so she was admitted to his care; but as she had diabetic ketoacidosis and was the first consultant's patient he decided to refer her to him. The first consultant had asked to be informed immediately when diabetic patients were admitted and took a keen interest in them. The second consultant was notified of Miss J's admission by the first registrar who told him that they had a diabetic patient with diabetic ketoacidosis, that she was getting better, but that they intended to transfer her to ITU for monitoring and management. He was told that he was not needed immediately and he said he would see her after a staff meeting. He so informed the first consultant and they both went to ITU. He asked the first consultant to take over Miss J's management and he agreed to do so. The second consultant did not notify staff formally that the first consultant had assumed responsibility for Miss J's

care: he did not feel he needed to because it was well known that he would do so in such cases and would make quite clear what the patient's future management plan should be. The Trust's practice was that patients were managed by the consultant specialist relevant to their condition under a 'shared care' arrangement.

28. The SHO and the second consultant had an evening ward round. They discussed Miss J's care, but the second consultant did not formally assess and review her, as responsibility for her care had been accepted by the first consultant. The registrar had updated the SHO and she in turn updated the second consultant. The SHO telephoned the second consultant at 8.46pm to tell him that Miss J had not been well. The SHO was concerned that the diabetic ketoacidosis had not resolved as anticipated and sought advice on how this might be improved. She also mentioned that Miss J had had an episode of headache and agitation, but that this was responding to simple analgesia. She felt that Miss J possibly had a low pain threshold. The second consultant advised the SHO to telephone the first consultant at home for advice. The second consultant telephoned the SHO at 11.30pm to check that all was well. The SHO said that Miss J was getting better and that she (the SHO) had talked to the first consultant. The alteration in treatment had improved Miss J's diabetic ketoacidotic state and at that time her headache was not presenting a problem. The onset of her headache struck the second consultant as unusual; but as it seemed to respond to simple analgesia it did not give rise to concern at that time. He did not know about the association of cerebral oedema with diabetic ketoacidosis. At 3.57am the SHO telephoned the second consultant and said that Miss J had deteriorated suddenly, was unconscious and needed to be ventilated. The second consultant instructed the SHO to ventilate the patient and telephone the consultant anaesthetist. The second consultant then went straight in and after assessing Miss J telephoned the first consultant at 5.15am.

29. The **first consultant** told the investigator that he saw Miss J on 22 July at 1.30pm in ITU. She was confused, although her mental state had improved since admission. She was not able to give him a history. She was very breathless, lying flat and drowsy. He noticed that her sodium was very low, but it rose quickly. Miss J was under the care of the second consultant, but the first consultant advised him. The first consultant saw Miss J three times during the day: she improved dramatically, and by 5.45pm was a lot better. He thought that her care had been managed appropriately. Clinical management fell within accepted protocols (guidelines for the treatment of particular conditions) for the treatment of diabetic ketoacidosis and was well understood by the staff concerned. The first registrar had followed the protocol, with minor variations. Miss J had persistent acidosis and it was consistently improving. The first consultant would have preferred to have been told about her headache at 8.00pm, but was not telephoned between 5.50pm and 9.45pm. If he had been contacted he might have considered pituitary apoplexy. He would have ordered a CT scan, but would not have considered cerebral oedema. In 15 years as a consultant he had had only three deaths, including Miss J's; and he had never seen cerebral oedema in an adult patient with diabetic ketoacidosis. The protocol has since been amended to add the risk of cerebral oedema and to emphasise the use of 10% dextrose.

Nursing staff

30. The **first staff nurse** explained that on 22 July she was in charge of the ITU day shift and took charge of Miss J's care. She had no experience of cerebral oedema associated with diabetic ketoacidosis. Protocols were kept on the ward including diabetic ketoacidosis guidelines. They were often referred to, and senior staff were aware of them. The first staff nurse would have had the protocol open by the patient's bedside for reference purposes. Miss J had been quite a difficult patient to manage, as she kept refusing nursing interventions and did not seem to appreciate the seriousness of her condition. Miss J reported a headache at about 8.00pm. She held her head and said, "I'm having a brain haemorrhage". The first staff nurse was unsure of the significance of Miss J's headache and unsure whether she was being 'over dramatic'. However, she contacted the SHO at once. Miss J's conscious level was constant and the first staff nurse did not suspect her neurological functioning. She told the second staff nurse on the night shift that Miss J's mother had asked for her daughter to be nursed by a female member of staff because she was a very private person and had not been an inpatient before. (Note: Miss J's mother disputes this account.) The first staff nurse could not recall writing a care plan. (Note: There is no care plan in the notes.) She commented that it had been a very busy shift and she had not had a break. There were three patients in ITU, and four staff, including one nursing auxiliary.

31. The **charge nurse** said that the skill mix that night had been inadequate. He was a G grade nurse and was working with two D grades. One was a junior who had worked in ITU for only a few months and had no ITU qualifications; the other an agency nurse who had worked in ITU before. The agency nurse had no formal ITU qualifications, but the charge nurse had a reasonable knowledge of her skills. He was the only qualified nurse on duty and was working with a locum SHO. The charge nurse said in evidence that he had drawn his concerns about the skill mix on that shift to the nurse manager in advance. The charge nurse also commented in his evidence on the absence of senior consultant management in ITU and that there was no clear policy on senior clinical patient ownership. He was told at handover that Miss J did not like to be cared for by male nurses. He observed that that was

the case and that she responded better to female staff. He therefore assigned her care to the agency nurse, though he would otherwise have cared for her himself. The charge nurse was satisfied that the agency nurse's experience and ability were sufficient and he oversaw the care of all patients on ITU that night. The admitting (second) consultant technically had patient ownership; but endocrine patients were normally referred immediately to the first consultant. Diabetic ketoacidosis cases were usually handled by the on call registrar who liaised with the on call (second) consultant. He was not present on the ward when, at 8.00pm, Miss J developed a headache, but was informed about it at handover. Miss J complained of a headache persistently during the shift and this indicated to the charge nurse dehydration or toxicity. He drew his concerns about Miss J's persistent acidosis to the attention of the SHO, who contacted the first and second consultants. He tested baseline reflexes a number of times, but there were no changes. Miss J was able cognitively and could count backwards.

32. The **second staff nurse** was a D grade agency nurse. She usually worked 4 or 5 shifts a week for the Trust, had done so for about a year and worked the night shift on 22 July. She normally cared for coronary patients. She was not aware of any treatment protocols on the ward. She administered fluids on the oral instructions of medical staff. Miss J had refused to be catheterised and had to be coaxed into accepting an arterial line. She talked about her boyfriend and how they were planning to marry. She asked for a commode, appropriately, and showed no evidence that she was confused. Miss J was very tired, but if she fell asleep she woke instantly: there was no change in her level of consciousness. The second staff nurse was not present at 8.00pm, when Miss J developed a headache, but was informed about it at handover. The SHO was in almost constant attendance. At about 2.00am Miss J went to the toilet, and then said that her head was 'awful' and at one point, 'quite out of the blue', said that she thought she was going to die. The second staff nurse said that she did not attach any particular significance to Miss J's headache. She thought it was simply the consequence of her high sugar levels, and it seemed to settle. She did not smell ketones on Miss J's breath until 3.00am. The second staff nurse wrote up the nursing notes and fluid chart after the shift ended. Staff had no break on the night shift.

33. Some of the staff interviewed commented that Miss J had refused some medical and nursing interventions during her admission. Her behaviour was described in evidence to the investigator in terms such as 'demanding', 'immature' and 'difficult'.

Findings

34. Mr J has complained that his sister's death could have been avoided and that mismanagement by the Trust and its staff contributed to the sad outcome. Specifically, he complains that Miss J was misdiagnosed; that she received inadequate education about management of her diabetes and monitoring in the diabetes clinic; and that her final illness was mismanaged in hospital including by over-administration of fluids causing cerebral oedema. My findings address each of these concerns.

Diabetic clinic

35. I consider first the first consultant's diagnosis of MODY. Mr J has complained that the diagnosis was incorrect. The first consultant said that although he entered a firm diagnosis of MODY in his notes, he still had in mind the possibility that Miss J might have slow onset type 1 diabetes. The external professional advisers in this case are clear that the diagnosis of MODY reached by the first consultant was wrong and that Miss J most probably had slow onset type 1 diabetes. They also advise that such a diagnosis can safely be reached only after a significant period of time. The first consultant did not record that he had an alternative diagnosis under consideration; and the diagnosis he did record was unequivocal. It is clear from the evidence, and is wholly unsatisfactory, that Miss J believed that she had MODY and that that was a firm diagnosis rather than a working hypothesis which would need to be kept under review.

36. Mr J also complained that his sister did not receive the education and information she needed: in particular, that she was not told about the difference between type 1 and type 2 diabetes, about hyperglycaemia and about diabetic ketoacidosis. The first consultant is clear, on the other hand, that he covered all but diabetic ketoacidosis. The nurse specialist also maintains that she provided information and education appropriate to type 2 diabetes, but was unable to demonstrate this from her records. At the very least, Miss J understood from what she was told that she had MODY; that she did not require insulin; and how to test her blood sugar. I am unable to determine with any degree of certainty, however, the full extent of the information the first consultant provided to Miss J and, as a consequence, whether important information was not provided. I note with approval that the diabetes clinic now operates a revised educational procedure to ensure that young persons receive the information and instruction they need and that this is documented. I **recommend** regular audit of the effectiveness of these measures.

37. Following my investigation I am satisfied that, given the diagnosis, the actions of the nurse specialist fell within the accepted standards for a nurse of her experience and I do not consider that she was in a position to challenge the first consultant's diagnosis. However, it is a matter of concern that inadequacies in her records mean that neither I nor she can be certain what information she gave to Miss J. I note

with approval that the nurse specialist has now taken steps to improve the standard of her record keeping and I **recommend** that she should follow the advice given by my advisers (Annex A - paragraph 41). I also urge the nurse specialist to take note of the advice given at the conclusion of the advisers' report (Annex A - paragraph 84) and that it is essential that all diabetic patients, regardless of type or severity, are taught to test their blood sugar at least once a day if they are unwell, and that it should be made very clear to them in what circumstances they should contact the diabetes clinic for advice.

38. Mr J also complains that the first consultant and the nurse specialist failed to monitor his sister's condition adequately. He maintains that Miss J's blood glucose and HbA1c measurements clearly indicated declining diabetic control and that, as a result, action should have been taken to alter her management. The first consultant has said that, even had he diagnosed type 1 diabetes at the outset, Miss J's care would not have been managed differently. My advisers agree, and have said that her HbA1c results revealed a slight deterioration in diabetic control, but that this would not have required a change in monitoring procedure. In Miss J's case I am advised that blood glucose monitoring would have been sufficient to reveal the serious metabolic deterioration that occurred after 14 July 1997. I am satisfied, therefore, that Miss J's diabetic monitoring by the first consultant and the diabetes clinic was within acceptable bounds. I do not comment in this report on the actions of the other clinicians who saw Miss J between 14 July 1997 and her eventual admission to hospital.

Inpatient care

39. I turn now to the care provided to Miss J during her admission to hospital. Mr J has complained that hospital staff should have been aware of the risk of cerebral oedema in association with diabetic ketoacidosis; that they failed to treat diabetic ketoacidosis appropriately; and that they administered too much fluid so causing cerebral oedema. He believes that staff should have responded differently to the onset of headache and should have observed his sister more closely.

40. Miss J was admitted with diabetic ketoacidosis; she also had hyponatraemia and was clearly seriously ill. In view of that, a consultant should have taken an active role in planning, managing and evaluating her care. Neither the first nor the second consultant considered himself to be actively directing and monitoring Miss J's care over the first 24 hours. They considered they were sharing care but did not meet together with the SHO to lead the management; they were content with the SHO variously contacting each of them for advice. If the first consultant was unable to be fully involved because he was not on call, consideration should have been given to transferring the patient to another unit. I understand that the ITU management arrangements in place at the time were designed to ensure the involvement of specialists in the care of patients being cared for there. However, one consultant should have had clear over-arching responsibility for coordinating all aspects of Miss J's care. I find it wholly unsatisfactory that that did not happen with the result that there was a degree of confusion, a lack of focus on a care plan, and a lack of clear leadership to doctors who were still in training. I am pleased to learn that ITU management arrangements have now been changed.

41. I acknowledge that Miss J's care was in accordance with the hospital protocol for the management of patients with diabetic ketoacidosis. However, protocols provide no more than guidelines for clinical management, and have to be seen in the context of the patient's developing condition. Miss J was an exceptionally difficult case and her condition did not improve as expected. There is no evidence that she was overloaded with fluid; but it is clear that staff failed to bring the acidosis under control. In such circumstances, a senior member of the medical staff should have considered whether other approaches to treatment were necessary. As it was, it was only after Miss J's condition had deteriorated that the second consultant reviewed her himself. I find this wholly unsatisfactory. I cannot say with any certainty, however, whether regular bedside assessment by an appropriately experienced senior clinician would have altered the outcome in Miss J's case.

42. Mr J has complained that his sister was over-hydrated and that that caused cerebral oedema. I am advised that the state of a patient's hydration, particularly in the absence of a central venous pressure line, is a complex matter to determine. My advisers differed slightly in their views as to whether Miss J's fluid balance was restored or remained in deficit. They agree however, that she was not over-hydrated.

43. I am advised that the insertion of a central venous pressure line is considered a pre-requisite if fluid balance and the rate of fluid infusion are to be monitored effectively, particularly when a patient has, as in this case, both hyponatraemia and diabetic ketoacidosis. I understand that unsuccessful efforts to insert a line caused Miss J distress and that, as a result, the first registrar decided not to proceed. I consider that the absence of a CVP line made it all the more important for an experienced consultant to have been actively directing treatment and personally monitoring progress with the SHO until the patient was out of danger. The first and second consultants did not counter the first registrar's decision: I find that that was unsatisfactory.

44. It is not possible to determine precisely why Miss J

developed cerebral oedema. She was clearly severely ill as evidenced by her profound hyponatraemia on admission. I am advised that the reason why cerebral oedema develops in some patients but not others is not clearly understood, but that it is recognised that fluid balance is not the only determining factor. The Trust's staff had little awareness of cerebral oedema in adults with diabetic ketoacidosis, and acknowledge that they did not perceive it as a risk in Miss J's case. I am advised that cerebral oedema is rare but widely recognised as a cardinal danger of diabetic ketoacidosis and it occurs more commonly in children than adults: I accept that advice.

45. When Miss J developed severe headache at 8.00pm on 22 July, I am advised that she probably had early cerebral oedema. Once cerebral oedema develops it usually results in death or severe neurological damage. My advisers have commented that the staff who were involved in Miss J's care in the ITU were generally unaware that cerebral oedema in association with diabetic ketoacidosis is a potentially life threatening problem or what to do if it is suspected. I appreciate that levels of knowledge vary about the relationship between cerebral oedema and diabetic ketoacidosis and my advisers **recommend**, and I agree, that advice about cerebral oedema should be included in the protocols for the management of diabetic ketoacidosis. I am pleased to note that the Trust has now included this in its protocols. They also advise regular neurological monitoring with the aim of detecting the early signs of cerebral oedema. Again, I agree. My advisers comment that cerebral oedema in association with diabetic ketoacidosis is a rare, but recognised condition in adults. Given that the Trust accepts for care patients with diabetic ketoacidosis and has on its staff a consultant with a special interest in diabetes (the first consultant), I consider that the first consultant at least should have been aware of the risk in relation to diabetic ketoacidosis with hyponatraemia and should have considered it. Had Trust staff made a provisional diagnosis of cerebral oedema appropriate to Miss J's symptoms and treated her accordingly, for example by a trial of Mannitol as my advisers suggest in paragraph 71 of their report, she might possibly have survived. In reaching this conclusion I realise that there are no studies to confirm or refute the value of this intervention. But an opportunity was, I believe, missed, in circumstances where once cerebral oedema developed death or severe neurological damage was the likely outcome.

46. I do have some concerns about the nursing care given to Miss J and I believe that there are important lessons to be learned. First, the standard of documentation was poor. Fluid charts were not completed accurately, yet they are vital when the patient is seriously ill as was Miss J and where restoration of fluid balance is an essential part of a patient's management; and a care plan was not completed. In addition, it was not entirely appropriate to allocate Miss J's care to a nurse without an ITU qualification. At the very least there should have been regular review and supervision by the charge nurse: but there is no evidence of this in the notes. Greater efforts should also have been made to ensure senior clinical review: and the SHO should have been made aware earlier of the treatment protocol. I am also concerned by the general tenor of remarks made about Miss J, whilst she was in intensive care. I do not consider that staff were aware of just how ill she was, nor did they fully understand the effect of severe diabetic ketoacidosis upon a person's mental and emotional functioning. Although I do not think it affected the outcome I do think the views nursing staff expressed about Miss J coloured, to some extent, their responses to her reports of pain and her behaviour. The first staff nurse, despite her personal reservations, responded appropriately by calling the SHO; and the SHO reported the headache to the second consultant. She did not mention it to the first consultant when she called him later, presumably because the second consultant had not considered it especially noteworthy being unaware of the risk of cerebral oedema in association with diabetic ketoacidosis. The second staff nurse did not report the onset of headache at 2.00am. The charge nurse said that Miss J suffered a headache more or less continuously throughout the shift and yet the impression gained by the SHO was that it was settling with paracetamol and, therefore, was not serious. I **recommend** that the nurse manager should reflect, with his staff, upon this episode of care as part of staff development.

47. I have considered all aspects of Miss J's inpatient care by the Trust. Taken together, the shortcomings I have identified indicate that her inpatient care could and should have been more expertly co-ordinated. However, I do not infer that these shortcomings caused or substantially contributed to her death. I uphold the complaint.

(b) the report of the independent review panel included, inappropriately, a statement that Miss J was in denial of her diabetes.

Documentary evidence

48. The report of the independent review panel that considered Mr J's complaints included the following advice from its clinical assessors:

'The complainant describes his sister as naïve and painfully shy. He said that she was extremely fearful when she attended the clinic for the first time and thought that she might die. He describes her as having a great weight lifted from her after being told that she would not need insulin injections. Information which had not been previously submitted but had been used in

an earlier complaint hearing against a general practitioner came to light in the course of the review (Note: this was subsequently proved by Mr J not to have been used at that review). This information was in the form of a letter of 2nd December 1997 from [the SHO] who writes, "Amongst other things, [Miss J's] mother informed me that she (the mother) had attempted to take BM [Stix] measurements in the 2 or 3 days prior to admission however [Miss J] herself had refused to let her mother do this and her mother had not forced [Miss J] to comply". The home blood glucose testing record book shows good values which are very consistent until the last entry of 14th July 1997 which shows a value of 11mmol. Thereafter there are no tests. We were told that [Miss J] did not do her own tests but that all of her tests were done by her mother. We consider that two inferences can reasonably be drawn from this information. Firstly it suggests that the patient had difficulty in coming to terms with diagnosis of diabetes, had realised that control was poor and that a progression of the diabetes had taken place so that insulin treatment was likely to be advised. This kind of anxiety is recognised to cause a reaction of denial of the diabetes in some subjects. Secondly [it] tends to support the view that she did understand the signs and symptoms of deteriorating diabetic control and recognised their significance.'

49. The panel concluded that:

*'Miss J's home blood glucose testing record book shows values consistently around 7mmol until the last entry of 14th July 1997 when it shows a value of 11mmol. After this it seems that no further tests were done, and, according to [the SHO's] written statement, Miss J refused to allow her mother to take any blood samples for testing after this date. The Panel considers that it is reasonable to deduce from this that Miss J had difficulty in coming to terms with the diagnosis of diabetes, and had realised (when the blood glucose began to rise) that the disease was progressing and that insulin treatment was likely to be advised. This kind of anxiety is recognised to cause a **denial reaction** to the diabetes in certain people.'*

Evidence of Mr J and his family

50. **Mr J** believes that the panel's conclusion that his sister was in denial of her diabetes was unjustified and unfair. He said that he had not been shown the SHO's letter, and had therefore not been given an opportunity to refute the assertion upon which it was based. He was annoyed that the consultant appeared to have 'floated' the idea that Miss J was in denial as a mitigating factor and that the panel had quickly latched on to it. Mr J said that his sister did not test her blood sugar more frequently when she was ill, or contact the clinic, not because she was in denial but quite simply because she had not been instructed to do so. He produced a number of signed statements from members of his family testifying that his sister always tested her own blood sugar and that family members had observed her doing so. The signed statements included one from Miss J's niece that her aunt had tried to test her blood twice on 17 July and had asked her to assist with timing and trying to read the result. They had, however, been unable to determine a reading, though the result seemed to lie between 7 and 9. Mr J said in evidence that his mother did not know how to test blood sugar and he supplied a letter from her GP confirming that she was not diabetic but merely had impaired glucose tolerance. His mother confirmed that she tried to test Miss J's blood sugar on only one occasion and that was when her daughter's GP asked her to do so shortly before the ambulance arrived to take her to hospital. She denied having told any of the doctors at the hospital that she tested her daughter's blood sugar; except on that one occasion, when her daughter was clearly feeling very ill and had refused to allow her to do so (see paragraph 20). Mr J thought that the method by which the evidence of denial was produced at the panel was unfair, and that the Trust had fabricated it.

The panel chairman's evidence

51. The **panel chairman** said that this was only the third panel she had chaired. She had not been provided with any training for her role before hearing this case, which was complex and involved the assimilation of a great deal of information. She and the other panel members tried very hard to deal thoroughly and fairly with the case. The panel chairman commented that, with hindsight, although she would still have included comment about denial she would have used slightly different language and made it very clear that it was just a theory and was not supported by hard evidence. She accepted that, as written, it did seem quite dogmatic and had not been expressed quite as she had intended.

52. The clinical assessors had expressed their very strong opinion that Miss J had been in denial. The chairman accepted, now, that the panel had got 'swept along' with this theory and made assumptions which, in retrospect, they probably should not have done. The panel had heard Miss J described as shy, innocent and naïve. She had been a late arrival to the family and was obviously cherished and 'protected' by her older brothers. It seemed from the letter submitted by [the SHO] that her mother tested her blood sugars for her. Miss J had apparently stopped testing her blood sugar when she became ill, and had been described as fearful of diabetes. She appeared to have refused to let her mother test her blood sugar when she was ill. On that basis, it seemed reasonable to conclude that Miss J was in denial. The panel wanted to try to understand, to explain how this

might have happened and to help the family come to terms with events. The panel certainly did not intend to add to the family's anguish.

53. The lay chairman could not recall precisely what evidence the panel had been given. She remembered seeing [the SHO's] letter, but could not recall seeing a written statement from the first registrar which contained similar information. The panel was not told that Miss J's mother did all the tests. The chairman believed that the clinical assessors had assumed that that was so. Denial had been a fundamental tenet of the clinical assessors' view and not one the panel could disregard or overrule. However, the chairman was clear that, in future, she would be more cautious and would ensure that conclusions expressed in panel reports were founded on the evidence.

Evidence of Trust staff

54. On 28 November 1998, the **first registrar** wrote in a signed statement:

> ' ... *At about 5.15pm I rechecked the blood gases, again with difficulty in obtaining the sample. [Miss J] was very unhappy about having yet another needle. At this stage her relatives were visiting, and while her Mother was present I asked [Miss J] if she had been checking her blood sugars at home in view of the fact that she had been unwell for several days. [Miss J] said that she had not checked her own blood sugar, and [her mother] said that she had been trying to encourage her to do so, but [Miss J] was unwilling to do so as she did not feel well enough, even having returned from a holiday in Wales after only two days as she felt unwell. [Her mother] said that she also is diabetic, and had offered to check the blood for her, but that [Miss J] had refused.*'

55. The first registrar said when interviewed that she had gained the impression that Miss J's mother intended to convey that her daughter had refused on more than one occasion. She thought her mother was saying that she had known something was wrong, but that her daughter would not let her test her blood.

56. The **SHO** explained that the Trust's medical director had asked her to provide a written statement and information about her communication with Miss J's family. She provided a written statement which set out her clinical involvement and, in a covering letter, dated 2 December 1997, her recollection of conversations she had had with the family. The letter included:

> *On admission I gained information from both [Miss J] and her mother about the preceding illness. Amongst other things, [Miss J's] mother informed me that she ([Miss J's mother) had attempted to take BM Stix measurements in the 2 or 3 days prior to admission however [Miss J] herself had refused to let her mother do this and her mother had not forced [Miss J] to comply.*'

57. The SHO told the investigator that she had talked to Miss J's mother when she admitted her and that she had asked questions about Miss J's blood monitoring history in order to establish the pattern prior to her admission to hospital. Her recollection in December, was that Miss J's mother had told her that she had wanted to test her daughter's blood sugar, but that Miss J had become upset and she had not wanted to force her. She understood this situation to have spanned a 2 or 3 day period. She was unable at this distance in time to recall the incident with any greater clarity. She would have needed to establish what Miss J's blood sugar levels had been over the preceding few days to determine whether her condition was a sudden onset or a gradual deterioration. She certainly had the impression that Miss J's refusal to allow her mother to test her blood related to a period of time rather than one specific occasion.

58. The **nurse specialist** said when interviewed that Miss J had been a shy person and generally came to clinic with her mother. She was co-operative; seemed to take information on board; was happy to receive it and to engage in conversation. She did not observe any behaviour that might indicate to her that Miss J was in denial; she thought she understood her role in the management of her own condition. Miss J answered questions appropriately, accepted her diagnosis, attended clinic regularly and tested her blood. There had been no 'no shows' or excuses not to attend clinic. The diabetes nurse specialist did not notice any changes in Miss J's emotional state over the period that she saw her.

59. The **first consultant** said when interviewed that he told the panel that he thought Miss J was in denial. He did not think she was in denial of diabetes, but thought she was in denial of transition from type 2 to type 1. She did not test her blood sugars when she was ill and would not let her mother do so. Miss J had told the GP that her blood sugars were '7'ish' when her last reading had been 11. She was vomiting for four days, ill for ten, and yet failed to contact the clinic. She was an educated and compliant woman.

Findings

60. Mr J has complained that the independent review panel's finding on the question of denial was both incorrect and unjust. He and his family had been upset by the implication that Miss J had contributed to her own death. Mr J believes that there were insufficient grounds to support the panel's conclusion and he contends that the panel did not test the evidence. The lay chairman accepts that the panel's conclusion should have been expressed differently: but she felt it important for the panel to reflect the

advice it had been given. I do not criticise the panel for doing so. It is important however, that in reaching a conclusion a panel should consider carefully whether it is supported by the evidence and whether all reasonable opportunities have been taken to test that evidence. I have done so in the course of my investigation and have taken account of the views of my adviser in clinical psychology (Appendix A) as denial is a psychological concept, an inference from behaviour. I am advised that it is generally accepted that particular patterns of behaviour can arise for a variety of psychological and other reasons. The first consultant invoked (during the IRP panel), and the panel accepted, a psychological account for Miss J's presumed failure to act. It was, therefore, appropriate for me to seek a psychologist's view on the evidence that a particular psychological process was implicated in Miss J's alleged failure to act. The consultant cited no independent evidence other than the presumed failure to act as the grounds for inferring denial. He did not at the time cite, let alone test, other possible explanations for Miss J's behaviour. I have concluded that Miss J was not in denial. The panel chairman has recognised that the panel's views on this matter were expressed unwisely. I am pleased that this is accepted. I do not believe that there was any deliberate attempt by the Trust to mislead the panel or to fabricate evidence. I uphold the complaint.

Conclusions

61. I have set out my findings in paragraphs 34 - 47 and 60.

62. There is no doubt that type 1 and type 2 diabetes are serious life threatening conditions. Equally, there is no doubt that if they are correctly managed the risk of premature death and complications can be substantially reduced. Yet Miss J died. This investigation needs to be seen in the context of those previously conducted by my office and through the NHS complaints procedure into the entire course of Miss J's treatment and care. From these it is clear that a number of mistakes were made beginning with the initial, unduly definite, diagnosis of type 2 diabetes. Avoiding any one of these mistakes would have improved Miss J's chance of survival. It is not possible for me to say that one or more of these mistakes individually led to her death: but taken together they almost certainly did. If, for example, the diagnosis had been correct or expressed with sufficient caution; if we could be certain that Miss J received the information and education she needed; if any one of the three GPs involved in her care had tested her blood or urine; or if Miss J had had impressed upon her, in no uncertain terms, that she must test daily when unwell, and had done so and reported untoward results, she might have survived.

63. This investigation has revealed that Miss J's inpatient care could have been more expertly co-ordinated and that she had a right to expect better from the Trust and its staff. For example, I have commented on the failure to insert a CVP line, on the failure to keep accurate fluid balance charts and on the lack of clear consultant leadership in ITU. I have also commented on nurse staffing and supervision in ITU and on the nurses inappropriate reaction to Miss J's behaviour. I cannot say with any certainty, what contribution, if any, these failings made to the tragic outcome in this case. It is not understood why some patients develop the rare condition of cerebral oedema and I cannot be certain whether different clinical management would have prevented this condition. I am advised that once Miss J collapsed as a result of cerebral oedema her death, or severe neurological damage was inevitable. I have also commented, however, that, in these circumstances, the diagnosis of cerebral oedema and the use of a trial of Mannitol should have been considered.

64. An important lesson from this case, is the need for all those involved in diabetic care, not least patients themselves, to be aware that it is essential to test blood glucose and urine ketones more frequently during an intercurrent illness, whatever the type or severity of diabetes. This simple measure could have saved Miss J: I hope it will save others.

65. The Trust has advised me that significant developments have taken place in diabetes care and education at the hospital in the last three years. The drivers for these developments have been a combination of the issues highlighted in Mr J's complaint and a wider series of significant service enhancements, which include:

-the appointment of a further consultant physician with a special interest in diabetes working with both secondary and primary care;

-successful primary and secondary care partnerships including for:

- diabetic foot clinics
- retinopathy clinics
- specialist nurse clinics
- pre-conception clinics
- ante-natal clinics
- young persons clinics

66. In relation to diabetic nursing, service development in the last three years, has included nursing documentation including the introduction of education check lists and follow up plans. Diabetes literature has been improved for both type 1 and type 2 diabetics which highlights greater awareness of sick day rules, pre-conception and pregnancy care and patients new to insulin therapy.

67. Many changes have also taken place in the delivery of critical care services at the hospital. These range from the introduction of a specific policy on the management of ketoacidosis and the modification and updating of fluid charts and results sheets. A review of nurse staffing levels has also taken place which has resulted in strengthened nurse leadership within the unit and robust plans for further nurse recruitment. This will support the transfer to a purpose built critical care facility with additional bed capacity and the provision of a high quality patient environment including relatives accommodation.

68. The Trust has asked me to offer to Mr J and his family its apology for the shortcomings I have identified. I do so through the medium of this report. The Trust has also agreed to act upon my recommendations in paragraphs 36, 37, 45, 46 and in Appendix A where action has not already been taken, including in the course of the service developments described above. I have also **recommended**, and am pleased that the Trust has accepted, that a meeting between senior officers of the Trust and Miss J's family would be a helpful way forward in deciding how the Trust might respond to the findings in my report.

M S Buckley
Health Service Ombudsman

August 2000

Appendix A

Report by the External Professional Advisers to The Health Service Ombudsman on Complaints from Mr J

First external professional assessor

Mrs P - MA RGN HV Cert

Relevant experience

Diabetes Nurse Specialist.

Second external professional assessor

Dr U - MB BS

Relevant experience

Consultant Physician

Third external professional assessor

Professor E

Relevant experience

Professor of Clinical Psychology

Fourth external professional assessor

Dr S - PLD, FRCP

Relevant experience

Emeritus Consultant Physician

Fifth external professional assessor

Ms J - RGN MSc

Relevant experience

Clinical Risk Manager

Introduction

1 We have been asked to consider whether the care and treatment provided to Miss J was adequate in terms of what might reasonably be expected of staff at a District General Hospital.

2 Our advice in relation to specific issues is set out below; one or more external professional assessors have contributed to each section. We have examined the nursing and medical records in detail; the papers provided by Mr J, the Trust and the investigator's interview notes.

Complaint (a) the care and treatment provided to Miss J by Halton General Hospital NHS Trust was inadequate

Miss J's care at the Diabetic Clinic

Clinical care

Initial diagnosis of maturity-onset diabetes of the young (MODY)

1 Miss J saw the first consultant in the general diabetic clinic in July 1996. She was not overweight and had not lost weight. The plasma glucose concentration and the haemoglobin A1c (HbA1c) percentage were both in the normal range. The consultant understood that two family members were diabetic: Miss J's mother and her maternal grandfather. The consultant diagnosed maturity-onset diabetes of the young (MODY). Miss J was told that the diagnosis was MODY; her clinic card had written on it "I have MODY diet controlled diabetes". The general practitioner was told that the diagnosis was MODY.

2 Miss J understood that a diagnosis of MODY meant that she would never require insulin. The diabetes nurse specialist taught her to test her blood glucose using reagent strips. She was advised to test her blood glucose about three times each week. She did not take any medications.

3 The diabetes nurse specialist and the first consultant recollect that Miss J was advised to test her blood glucose frequently - at least daily - if she was in any way unwell. Miss J's brother states that she did not receive this advice. Miss J was not advised to test her urine for ketones if she was unwell.

4 The first consultant saw Miss J at intervals in the young persons diabetic clinic. When she was seen at the clinic the haemoglobin A1c (HbA1c) percentage was measured.

5 Miss J measured her blood glucose reasonably regularly up to the 14th of July 1997. Her results do

not show significant worsening of her diabetes apart from the final result, which was 11 mmol/L. The diabetic clinic haemoglobin A1c results show slight worsening of her diabetes in 1997 compared with 1996.

Discussion

6 When Miss J, a 19 year-old, presented with diabetes mellitus it was not necessary to make a diagnostic choice as to the type of diabetes as her diabetes could have been managed quite satisfactorily as 'diabetes mellitus, type unspecified'. In time the true diagnosis would have become apparent.

7 There were two possible further diagnoses: Maturity-onset diabetes of the young (MODY) and type 1 diabetes. Type 1 diabetes is also known as insulin-dependent diabetes mellitus (IDDM). These diagnoses are mutually exclusive. Maturity onset diabetes or non-insulin-dependent diabetes mellitus (NIDDM) is now referred to as type 2 diabetes.

8 MODY is an inherited type of diabetes with onset in adolescence to young adulthood. It is genetically and phenotypically heterogeneous. Some phenotypes are not benign as the diabetes may progress with age, requiring treatment with insulin and causing microvascular complications. Ketoacidosis does not occur in MODY.

9 Type 1 diabetes is more common than MODY in adolescents and young adults. The underlying pathology is autoimmune destruction of the insulin-secreting beta-cells in the pancreas. If the diagnosis of diabetes is made when a considerable number of beta-cells are intact the diabetes may be well controlled without treatment until such time as a significant decline in beta-cell numbers occurs. Progressive loss of beta-cells is associated with deterioration in metabolic control, which, when severe, results in ketoacidosis. In most type 1 diabetics dependence on insulin develops within one year of diagnosis; in some it may take years to develop.

10 These two types of diabetes cannot be distinguished with certainty on clinical grounds at the time of diagnosis. If diabetes can be managed for a prolonged period - several years - without insulin MODY becomes the more likely diagnosis.

11 Laboratory tests can aid diagnosis: in some, but not all forms of MODY genetic defects can be identified, and in type 1 diabetes circulating antibodies to insulin and pancreatic islet cell components can be detected. These tests are not routinely available.

12 A diagnosis of MODY could only have been made when Miss J presented with diabetes if type 1 diabetes could have been excluded. She was, however, given a diagnosis of MODY without type 1 diabetes having been excluded.

13 By being given the diagnosis of MODY Miss J was not made aware of the risk of metabolic deterioration to ketoacidosis which can occur in type 1 diabetes. She was not told about testing for ketones in urine if the blood glucose is high. She was given advice appropriate for a type 2 diabetic. It is not known if the symptoms of uncontrolled diabetes were explained to her.

14 In fact, regular monitoring of the blood glucose with regular checks of the haemoglobin A1c was an appropriate way to monitor Miss J's diabetes provided she was not unwell. In both type 1 and type 2 diabetes metabolic deterioration occurs during intercurrent illness so that all types of diabetes require frequent blood glucose monitoring during illness of any sort. In Miss J's case blood glucose monitoring alone would have been sufficient to reveal the serious metabolic deterioration after the 14th of July 1997.

Conclusions

15 It was an error for the consultant to give Miss J a diagnosis of MODY in July 1996. The consultant should not have excluded the possibility of type 1 diabetes developing slowly. If he had included this possibility Miss J would have been made aware of the risk of ketoacidosis. This might have altered the way she responded when she became unwell in July 1997. It might also have altered the way the general practitioners, whom she saw when she was unwell, responded. The HbA1c results revealed that there was a slight deterioration in diabetic control which would not require anything other than a continuation of a watch and wait policy and monitoring.

Recommendations

16 The diagnosis of maturity-onset diabetes of the young should be made only when type 1 diabetes has, essentially, been excluded.

17 Both general practitioners and physicians should be vigilant as a small number of diabetics considered to have MODY or type 2 diabetes may in time turn out to have type 1 diabetes.

18 Diabetics and general practitioners must be aware of the risk of metabolic deterioration in association with intercurrent illness. Appropriate monitoring of the diabetes is mandatory.

Compliance

19 Compliance in medical usage means acting in accordance with rules, plans or advice.

20 Miss J was advised to measure her blood glucose

approximately three times each week. The exact advice was not recorded. Miss J did measure her blood glucose frequently. The most common interval between tests was four days, followed by three, and then five days. There were occasional intervals of several weeks when she did not record any results. These appear to have occurred when she was on holiday - and feeling well. As far as we can ascertain Miss J was very careful with her diet. Her compliance with the advice she had received was good until she became unwell in July 1997.

21 After recording a blood glucose result of 11 mmol/L on the 14th of July Miss J attempted to test again on 17 July but could not read the result and then did not test her blood glucose again even though she became progressively unwell.

22 Why Miss J did not test her blood glucose between the 17th and the 22nd of July is not known.

Discussion

23 In general Miss J followed the advice that she was given. What happened after the 17th of July 1997 is a mystery. We do not know for sure what she was advised to do if she became unwell; the right advice was to check the blood glucose at least once daily. We do not know what she was advised to do if the blood glucose results were high; the right advice was to contact the practice nurse or her general practitioner. We do not know if she knew the symptoms of uncontrolled diabetes: thirst, frequent urination, tiredness and weight loss.

Conclusion

24 We can come to no clear conclusion about compliance during the week before Miss J presented with severe diabetic ketoacidosis. Before then her compliance was good.

Nursing care

25 We have been asked to consider the role of the diabetes nurse specialist in the initial diagnosis of MODY, the subsequent educational programme and monitoring of diabetic control.

26 Miss J was diagnosed as a type 2 diabetic (MODY).

Discussion

27 The diabetes nurse specialist, with less than two years experience in this post, would have had little exposure to the management and possible progression of MODY. Although more information is now being published about MODY, in 1996 we would consider that the diabetes nurse specialist would not have had easy access to this little reported yet complex subject. A more experienced nurse may have asked for further clarification but we do not find it unreasonable that the diabetes nurse did not challenge the consultant's diagnosis.

Conclusion

28 We do not consider that the diabetes nurse specialist can be held accountable for the diagnosis.

Recommendation

29 It is useful for members of the diabetes team to have regular meetings to discuss unusual or complex patients. This acts as an educational process for the health professionals and ensures that there is agreement about the advice given to the patients, the treatment plan and parameters of control before further intervention.

The education programme and monitoring

30 Diabetes education began at the GP surgery and by the time Miss J saw the diabetes nurse at the hospital, she had been subject to several consultations concerning diabetes. The education programme initiated by the diabetes nurse specialist was that related to type 2 diabetes. Although not present during the first consultation, she saw Miss J at the clinic and once at home.

Discussion

31 The diabetes nurse specialist's records were very brief and it is not possible to determine precisely what information was given to Miss J. She said that she gave both verbal and written information about diabetes: Mr J disputes the content of both. Over the years there has been a wealth of diabetes literature published by many of the pharmaceutical and product companies concerned in diabetes care. Leaflets and booklets covering a wide range of diabetes topics have been renamed and redesigned and have readily been used by diabetes nurse specialists for patient education. If Miss J received "Diabetes, Diet and Tablets" (although no longer published, it was in print throughout the early nineties), then there is a section on illness and deterioration of diabetes control.

32 The diabetes nurse specialist did not record the level at which Miss J was supposed to contact them. The evidence given, at various times during the different stages of investigation of Mr J's complaint, has varied. The consultant and the nurse have said that Miss J would have been told to report a reading of 9, 10 or 11 and that she was told to test 2-3, 3-4, or 4-5 times a week. In the event she tested approximately every 3-5 days which roughly accords with the advice stated to have been given.

33 Miss J contacted GPs when unwell and told them that she had MODY. She does not appear to have told them that her last recorded reading was 11mmols.

34 The diabetes nurse specialist told the investigator

that when teaching someone, like Miss J, to test their blood she would tell them what the normal range was and that they would expect their fasting blood sugar to be 4-7, their pre-meal reading to be 4-7 and her random blood sugar to be not above 9. If their readings were regularly above that (i.e. more than 2-3) or if there seemed to be a different pattern to the results they should let the clinic know. Miss J was told to test 2-3 times a week. If they got a high reading, for example 11, they would be advised to test again the next day if they felt well or later that day if they felt unwell. They would always be asked to consider how they were feeling. She would explain that the reason they were testing was to avoid hyperglycaemia; they would be encouraged to understand their normal levels so that they had a pattern against which to compare.

Conclusions

35 It is possible that by April 1997, more frequent monitoring could have been advised because of the rising HbA1c. This could have produced an opportunity to further discuss any appropriate treatment changes but the change was relatively small and the nurse was not in error to continue with the regime already implemented.

36 We do not find the diabetes nurse specialist remiss for not teaching ketone testing and its relationship to diabetic ketoacidosis in this situation of education based on type 2 principles. It may be argued that should this information have been imparted it is unlikely that it would have been remembered. Therefore the awareness of change if unwell or not is a more important message. We can not tell from the evidence whether or not this information was given to Miss J.

37 What clinicians are looking for, is an altered pattern of results, not a single deviation from the norm. The diabetes nurse specialist did not remark upon an earlier instance of a reading of 11 in the notes, but she did record 'one odd one of 9mmols' which indicates that the reading had significance for her. We cannot determine, from the evidence, precisely what Miss J was told. All we can be sure of is that the diabetes nurse specialist did not fully document her discussions with her patient. 'Info. given' and 'general chat' are not sufficiently specific.

38 If one were to speculate, however, it would seem unlikely that Miss J would have been told to report a single high reading but would rather have been advised to report more than one. She recorded a single high reading on 14 July and when she tried to test again, she thought, according to her niece's evidence, that the reading was between 7-9. By the time she might next be considered due to test, she was feeling unwell and had consulted GPs on four occasions who did not themselves test her blood sugar or advise her to do so. The fact that Miss J did not report a single high reading of 11mmols is, therefore, not evidence that she received inadequate education.

39 The diabetes nurse specialist has accepted that her documentation was insufficient and she has taken steps to improve it. The standard of her note keeping is not in fact any less than that of many nurses in practice and falls within the norm. However, this case has demonstrated that that standard, in diabetic care, is not itself adequate. On balance, and being careful not to judge her actions with hindsight, we do not think that the diabetes nurse specialist provided inadequate care to Miss J. Clearly, if the diagnosis had been different, so too would the level of information provided to Miss J.

Recommendations

40 As there is a diverse range in the quality of printed diabetes educational materials as provided by companies, it may be more prudent for a diabetes team to agree to standardise and print their own. This has financial implications but would prevent inappropriate or out dated material being used.

41 We recommend that nurses should record that they have taught normal/abnormal parameters of control; advised the patient to contact them if they record x number of results which deviate from the norm at a level of x, and told them to test x times when feeling ill. We understand that nurses find it difficult to find time to document their care as well as deliver it, but records are a vital nursing tool - they act as an effective check-list against which a nurse can evaluate whether they have provided all the care/information they intended. They are the means by which a nurse can act as a fully accountable practitioner and demonstrate the fact.

Admission and initial management of diabetic ketoacidosis

Clinical care

Discussion

42 Miss J was seen by the SHO within 15 minutes of admission on the morning of 22 July. The SHO made a rapid, detailed assessment of her patient, diagnosed severe diabetic ketoacidosis, requested all appropriate investigations and instituted initial resuscitation measures. Within the hour she had discussed the situation with her immediate senior colleague, the first registrar, and met the parents to explain that their daughter was seriously ill and, on the registrar's advice, would be transferred to ITU. The SHO had no further involvement with Miss J's care until late afternoon.

43 The SHO was employed as a locum and was new to the hospital. The SHO told the investigator that she had not received any formal induction on taking up

her locum post nor was she made aware of any protocols for the management of common medical emergencies until 11.00pm that night. Her management was based on her previous experience of caring for people with diabetic ketoacidosis.

Conclusion

44 The SHO's initial assessment and management of Miss J cannot be criticised. She gave exemplary care to Miss J and her immediate family.

Recommendation

45 All new and locum personnel should receive formal induction into the working practices of the medical department which should be centrally co-ordinated. This should include protocols for the management of common medical emergencies which should be available in all areas where such emergencies are likely to present for care.

Admission to ITU and further management of diabetic ketoacidosis

46 Following admission to ITU, the first registrar attempted to insert a CVP line to monitor Miss J's fluid balance but she was unsuccessful. She decided that a CVP line was not essential partly to avoid further distress to Miss J and because her pulse, blood pressure and urine output were considered satisfactory. Miss J declined a urinary catheter and the first registrar complied as her urine output was copious. The consultants were aware of her decision and did not reverse it. The first registrar also asked an anaesthetic SHO to insert an arterial line but this too was unsuccessful.

47 The first consultant told the investigator that he viewed his role as advisory. He saw Miss J on three occasions during the day and provided telephone advice during the evening. The second consultant said that he understood the first consultant to have taken over clinical responsibility for Miss J and as a result did not assess her himself until after her collapse at 3.00am. He had indirect involvement in the patient's care.

48 The first consultant's notes were of an advisory nature. There was no clear documented management plan. The SHO was not aware that there was a diabetic ketoacidosis management protocol until 11.00pm. The first consultant was not aware that the SHO did not have access to this protocol according to his written statement.

49 At 6.00pm the SHO resumed responsibility for Miss J's care. There was a locum registrar (the second registrar) on duty but he had no direct involvement before Miss J's collapse apart, from one telephone discussion with the SHO.

50 At 8.00pm the SHO was called to ITU because Miss J had developed a severe headache. The SHO noted that her metabolic state had not improved and was unsure which advice to follow. She called the second consultant who advised her to call the first consultant at home. She successfully contacted him at 9.40pm and he advised a change in treatment (see paragraph 18 main report). By 11.30 Miss J appeared settled. At 3.30am she was called urgently to ITU because Miss J had collapsed.

Discussion

51 When a patient presents with severe diabetic ketoacidosis in a state of mental confusion, significant dehydration and a high urine flow most diabetologists and critical care physicians would consider a CVP line a prerequisite for the proper assessment of intravascular fluid status and the rate of fluid replacement needed. Likewise, the necessary, frequent measurement of electrolytes, pH and blood pressure to monitor the effects of therapy often necessitates the use of an arterial line. The first registrar initially, correctly concluded that both were desirable. She was deflected from achieving her objective by the practical difficulties of inserting them, which may have been the result of inexperience in practical procedures, and a desire not to cause her patient further distress. Her consultant colleagues concurred with her decision and should have realised that this made their own active role in the supervision of Miss J's monitoring and management all the more important.

52 By late afternoon the patient's acidosis was not significantly better, nor had she received adequate fluid replacement. The consultant was clearly concerned about her potassium level and pH. His notes, however, are of an advisory nature. There was no clear, detailed plan of management entered in the notes with set parameters, targets and related instruction. As a consequence, the SHO who had received conflicting advice, was unclear what action to pursue and was unaware that there was a treatment protocol.

Conclusion

53 Overall, the ITU management of Miss J's diabetic ketoacidosis was satisfactory from the point of view of her electrolyte status but her fluid balance and acid-base derangement were never adequately assessed or fully and rigorously attended to. In a case of diabetic ketoacidosis there may be a deficit to the equivalent of five or more litres of normal saline. In Miss J's case, according to the available fluid records, and (allowing for inaccuracies in the nursing fluid charts), there was a negative balance (if insensible loss is taken into account) during the first nine hours of treatment and even by the twelfth hour of care there was less than a litre positive balance. Thus the use of a CVP line would have been invaluable in assessing both the status of her

intravascular volume and fluid requirements. The pH never improved significantly during the first twelve hours of therapy. The use of 8.4% sodium bicarbonate is debatable. Intensivists working in an ITU would probably be confident in giving boluses of such bicarbonate strength, but, in general, most diabetologists would err on the side of caution and give only 1.26% or 2.8% at the most, and tentatively. The administration of bicarbonate runs the risk of lowering the potassium, producing a fall in the pH of the cerebrospinal fluid (increasing brain acidosis) and impairing the level of consciousness. The SHO was unsure as to what to do with regards to Miss J's acidosis. In fact, the 'front line' doctor care for Miss J on the ITU was being supplied by three junior doctors; a locum SHO, a locum Registrar and a locum anaesthetic SHO, all of whom acquitted themselves well for their level of expected competence.

54 Neither of the senior doctors considered that he had responsibility for overseeing Miss J's total care, indeed each thought that the other was responsible. The first consultant, in his written statement, seemed under the impression that the SHO was following the hospital protocol for the management of diabetic ketoacidosis: this was not the case. As a consequence, the SHO was unsure how to proceed with Miss J's care at a time when she had been receiving therapy for over ten hours and yet her acidotic state had not improved and, despite the SHO's best efforts it was almost two hours after she was called to the ITU at 8.00pm to review Miss J that the SHO finally received further instructions concerning a change in therapy for tackling the continuing acidosis. Only after Miss J's condition had deteriorated did the consultant physician on call (the second consultant) review her himself. Whether regular, at the bed, assessments by a senior doctor would have altered the outcome of Miss J's admission is open to speculation.

Recommendations

55 Any person admitted to hospital with a serious, life-threatening condition such as diabetic ketoacidosis should have their case reviewed by a doctor of registrar status or above. Where a case of diabetic ketoacidosis does not respond to therapy in the expected manner there should be available a consultant with an over arching responsibility for coordinating all aspects of medical care. The consultant on call should always adopt a 'need to know' policy as to who has specific responsibility for this over arching role. In this particular instance this does not appear to have been the case. There must be a clear, consultant led, management plan.

56 Where a person in a state of diabetic ketoacidosis is not, within a few hours of treatment starting, positively to progress with a steady rise in their pH, a senior doctor should be available, in person, to reassess the situation and look for causes of continuing acidosis; for example lactate build up, hyperchloraemia or inadequate fluid replacement. It should never be the case that an on call SHO has responsibility for the ITU management of such a serious condition as diabetic ketoacidosis.

Hyponatraemia

57 When Miss J was admitted to the hospital on the 22 July 1997 the initial tests in the minor injuries unit revealed hyponatraemia in addition to acidosis (arterial pH 7.09). The serum concentration of sodium was 109 mmol/L, potassium 6.7 mmol/L, creatinine 186μmol/L and glucose 38.8 mmol/L. Treatment with insulin and with 0.9% saline solution, given intravenously, was started at about 11.00am.

58 By 3.00pm the volume of saline infused was between 2fi and 3fi L. The record of infused fluids over this period was inadequate. By 1.30pm urine flow was good, suggesting that the extracellular compartment volume had been restored. By 3.00pm the serum concentration of sodium was 122 mmol/L with potassium 4.9 mmol/L, creatinine 108μmol/L and glucose 14.2 mmol/L. The central venous pressure was not monitored; an attempt to insert a cannula had failed. No explicit treatment plan was formulated.

Discussion

59 Hyponatraemia is defined as a serum sodium of less than 136 mmol/L. Hyperglycaemia causes translocational hyponatraemia; the presence of a high concentration of glucose in the extracellular compartment decreases the serum sodium concentration by shifting water from the intracellular compartment to the extracellular compartment. [This reduction is 3.0 mmol/L of sodium for each 10 mmol/L increase of glucose. This leads to a net increase in osmolality of approximately 3.6 mOsm/Kg for each 10 mmol/L increase of glucose.]

60 Miss J was clearly much more hyponatraemic than expected purely on account of the translocational effect of hyperglycaemia. Her serum osmolality was below normal. The probable cause of this component of the hyponatraemia was that she drank a lot of water when she was dehydrated and sodium deficient. Hypotonic hyponatraemia does cause brain swelling. It is of considerable interest that hyponatraemia has been reported in a high percentage of patients with diabetic ketoacidosis who develop cerebral oedema.

61 Treatment of ketoacidosis with insulin and the restoration of the extracellular compartment volume with 0.9% saline solution take precedence to concerns about hyponatraemia per se in diabetic ketoacidosis. However, it is prudent to avoid rapid administration of 0.9% saline after the extracellular fluid volume has been restored to normal in order to avoid a rapid increase in the serum sodium

concentration which can occur in the presence of high urine output. Neurological sequelae following rapid correction of hyponatraemia include pontine demyelination which is associated with shrinkage of the brain as the serum sodium concentration rises. The infusion of 0.9% saline does not cause an increase in the intracellular compartment volume; infusion of excess saline does not cause brain swelling.

62 In this situation the measurement of the central venous pressure would have been most helpful in guiding the rate of fluid replacement.

Conclusion

63 Miss J had significant hyponatraemia; more than could be explained by hyperglycaemia. This was an additional factor reflecting the severity of her metabolic disorder. It increased the risks of neurological problems occurring during corrective treatment.

Recommendations

64 A physician with experience of diabetic ketoacidosis and hyponatraemia should manage a case of this nature. A careful treatment plan is needed with estimates of the deficits of water, sodium and potassium. Objectives should be set and progress monitored frequently.

65 Regular neurological monitoring is required in severe diabetic ketoacidosis, particularly when hyponatraemia is present.

Cerebral oedema

66 At 8.00pm on 22 July Miss J developed a severe headache. She was agitated. Her conscious level was said to be normal; she had been somewhat confused when she was first admitted to the hospital. Treatment with insulin and intravenous fluids had started about 9 hours before the headache developed. Miss J was given some Paracetamol. The headache settled after about one half hour.

67 The headache recurred at about 2.00am the next morning. Within 10 minutes Miss J's conscious level had deteriorated and after 30 minutes she was unable to sustain adequate respiration. At this point the neurological catastrophe was irreversible.

Discussion

68 Children, occasionally, and young adults, rarely, die suddenly from the rapid onset of neurological coma during treatment for diabetic ketoacidosis. This neurological catastrophe - cerebral oedema - tends to occur between 8 and 24 hours after the initiation of treatment. Treatment often appears to be going well. The outcome is usually death, occasionally recovery with severe neurological damage.

69 Brain swelling has been shown to occur generally in diabetic ketoacidosis. During treatment to reverse the dehydration, acidosis and hyperglycaemia the brain swelling increases. The catastrophe occurs when the cranium can no longer accommodate the expanding brain. Why brain swelling occurs in all cases of ketoacidosis but the syndrome of cerebral oedema in very few is not understood.

70 There is no consensus as to the cause of cerebral oedema. It occurs in severe ketoacidosis not in hyperglycaemia per se, even with extremely high glucose levels. Those who present with hyponatraemia and ketoacidosis have an increased risk of developing cerebral oedema. There is a suggestion that excessive fluid replacement may be a causative factor, (it should be noted that 0.9% saline and glucose solutions have quite different effects). Rapid correction of hyperglycaemia has been suggested as a factor leading to brain swelling; many advise slow correction.

71 If diabetics with severe ketoacidosis and those with associated hyponatraemia have regular neurological observations close monitoring may pick up early signs of cerebral oedema. Treatment to reduce brain swelling can then be considered in suspect cases. Treatment could include intravenous Mannitol, a reduced rate of fluid administration and mechanical hyperventilation. There are, however, no studies to confirm or refute the value of these interventions.

72 When Miss J developed severe headache at 8.00pm she probably had early cerebral oedema. She certainly had cerebral oedema by 3.00am the next morning when the headache recurred.

73 The medical staff, who were involved in Miss J's care were generally unaware of cerebral oedema as a potentially life-threatening problem and appeared to have little idea of the action which could be considered if cerebral oedema was suspected. Eventually dexamethasone was given both for cerebral oedema and possible pituitary apoplexy.

Recommendations

74 Young adults as well as children, with severe diabetic ketoacidosis, should have regular neurological monitoring with the aim of detecting the early signs of cerebral oedema.

75 Advice about cerebral oedema should be included in the protocols used for the management of diabetic ketoacidosis by all intensive therapy units that might look after young adult diabetics or children with diabetes.

ITU nursing care

Discussion

76 It is of concern that the fluid charts were not maintained accurately. It is particularly important to keep an accurate record of fluid balance in relation to any disorder where large volumes are infused and where the output (urine) materially alters the plans for input.

77 There is no evidence that a care plan was drawn up for Miss J, the care provided by nursing staff was commensurate with the directions they received from medical staff. It is a matter of concern that the coordination and monitoring of Miss J's care was left solely to the SHO, even though she was a locum and unsure as to how the care should be fully managed. It is reasonable to expect ITU staff, particularly at senior level and in charge of a unit, to be aware of any patient where there is clear evidence that treatment regimes are failing to have an impact on the underlying clinical presentation. In this particular situation where there was a significantly deteriorating metabolic acidosis which was not responding to treatment, it is reasonable to expect that the nursing staff should equally take steps to address the issue which might necessitate the facilitation of a more senior medical review. Such action should have been linked to an agreed formal plan of treatment and nursing care plan along with frequent reviews of progress against outcome objectives.

78 Under the Code of Professional Conduct, nurses have a responsibility to raise issues of concern regarding patients to more senior clinical staff if they see fit. Miss J's fluid replacement/balance and continual metabolic derangement should have prompted such action.

79 The standard of nursing notes is reasonable. We note however, that the accounts of Miss J's headaches as recorded in the notes do not match the staff's or family's descriptions given in evidence. It would have been helpful if they had recorded the location of the headache (occipital region) and the sensations of doom reported by the patient. Miss J reported that she felt as if she was having a brain haemorrhage and later that she felt that she was going to die. With hindsight, it is clear that Miss J was suffering a neurological catastrophe. The impression given by the nursing notes is that she suffered a relatively minor headache which settled with Calpol and that was the impression gained by the SHO. The charge nurse said that the patient suffered a headache more or less continuously. The headache at 2.00am was not reported to medical staff. The first consultant said that he was not aware of the headache and that he would probably have suggested a CT scan, although he would not have thought of cerebral oedema.

80 Of particular concern is the evidence which suggests that staff had formed a less than favourable view of their patient and therefore to some extent appear to have imposed value judgments upon the information she provided. She was viewed as a 'difficult' patient obstructing her care by refusing interventions. It appears that this coloured the staff's response to her reports of pain; pain is a subjective experience and it is essential that the patient's experience is both believed and acted upon, not interpreted by staff. Miss J was extremely ill and the metabolic imbalances caused by her acidotic state were bound to affect her mental and emotional functioning. It appears from the evidence, that staff did not understand how ill Miss J was or how this was likely to make her feel. Although this was unlikely to have affected the outcome in this case it would be useful for staff to reflect upon this episode of care as part of developing professional practice.

81 We note that Miss J's care was allocated to an agency staff nurse with no formal training or qualifications in ITU. We accept the reasons for allocating her care to a female member of staff in view of Miss J's preference and note that the charge nurse, in his evidence, has stated that he maintained a watching brief over her care. It was not however, entirely appropriate for such an ill patient to be allocated to a less experienced member of staff. There is no evidence in the notes that her care was being supervised or reviewed. It must be incumbent on the nurse in charge of the unit to be aware particularly of any patient whose condition is giving rise to concern.

Conclusion

82 We are satisfied that the care provided was adequate, save for the proviso in paragraph 79 above. Nursing staff must be proactive in supervising the care of sick/deteriorating patients under their care.

Recommendation

83 We recommend that the nurse manager take steps to address the shortfalls which we have identified, including through staff training, to improve the standard of care.

Final conclusion

84 We were asked to consider whether the care and treatment provided by the Trust to Miss J was inadequate. In providing our advice, we have had two considerations in mind: first, whether the standard of care was that which might reasonably be expected at a District General Hospital; and second, whether there were any useful lessons to be learnt in terms of 'best' practice for the future benefit of patients. We have concluded that the consultant was in error in making a diagnosis of MODY without first excluding slow onset type 1. Miss J's management in the diabetic clinic was adequate, and would not have been different even had the correct diagnosis been

made, but the education given to her would have varied. This case highlights the extreme importance of ensuring that everyone involved in diabetic care, patients, doctors, GPs and nurses are aware that it is essential to test blood glucose more frequently during an intercurrent illness, regardless of the type or severity of diabetes.

85 Following admission to hospital we have concluded that the care and treatment provided was flawed. Cerebral oedema is a complex condition and the direct causes are not understood. Cerebral oedema in association with diabetic ketoacidosis in adults is a comparatively rare but recognised condition. Once it had developed the Trust did not mismanage her care to any significant extent. We do think, however, that the presence of hyponatraemia in association with severe diabetic ketoacidosis should have ensured that Miss J's care was closely controlled by a consultant because of the increased neurological risk. We therefore conclude that her care should have been better managed although we cannot say whether this would have altered the outcome.

(b) the report of the independent review panel inappropriately included a statement that Miss J was in denial of her diabetes.

Denial

Context

86 Miss J was advised on the management of her diabetes by the first consultant and diabetes nurse specialist. In the week or so before her death, Miss J was unwell and became increasingly ill, eventually requiring emergency hospitalisation and intensive care. Near the beginning of that period, she saw her own and other doctors several times before eventually being admitted to hospital. Miss J's care at the Trust was considered by an independent review (IR) panel under the provisions of the national NHS complaints procedure.

87 The first consultant in his evidence to the IR panel noted that Miss J's "diabetic control had always been extremely good", but said also that "he realises that he did not understand [Miss J's] psychological makeup and that she was probably frightened of becoming insulin dependent, and perhaps went into some kind of denial when she realised her blood sugar was rising".

88 The IR panel's clinical assessors said in their report that "denial" by Miss J could be implicated in what happened to her. In their view, "Denial of diabetes and the need for insulin therapy is a common feature .... particularly in those young people of the patient's age.".

89 It is the assessors' view that in the special atmosphere created by the diagnosis of MODY, a "too relaxed view" was engendered in many people and "the understandable fear of insulin on behalf of the patient must also have contributed to the delay which occurred in seeking and achieving appropriate management."

90 In his letter of 17 March one of the IR panel members said that both he and his colleague were "in agreement that there was a strong likelihood that such denial took place" and "possibly" led Miss J to fail to act in a way that would protect her from the adverse outcome of her illness.

91 These accounts are the context for the IR panel's presumption that "denial" played a role in the events that led to Miss J's death.

92 It also needs to be noted that in the period just prior to her hospitalisation and death, Miss J was looking forward to a special event, going away for a week- end, the first time with her fiancé, to join his cousins at a holiday park to celebrate a birthday.

Self monitoring regime

93 We have two accounts of the self monitoring regime commended to Miss J. The diabetes nurse specialist stated that her advice to her would have been that for "values of blood sugar between 4 -7, she would be advised to undertake fasting blood sugars, whilst [for values from] 7 to 9 she should do random blood sugars. Generally, she should test her blood 4-5 times a week, more often if she went on holiday or was ill, or if anything else arose which disrupted her usual routine."

94 Miss J's brother reports that the diabetes nurse specialist at a Trust interview on 30 March 1999, confirmed that blood glucose monitoring "would be perfectly safe and acceptable every 4-5 days"; that if going on holiday Miss J "would only need to carry out a blood glucose test before she went away and after she returned", "to monitor more frequently when ill"- an instruction refuted by the family; and that the diabetes nurse specialist confirmed that she had no "worries or concerns with [Miss J's] ability to monitor blood glucose levels indeed [Miss J's] diary entries can be confirmed as being accurate by the HbA1c readings recorded at the [hospital]". The diabetes nurse specialist "did not have any concerns about Miss J's condition psychologically or physiologically at any of their meetings."

95 These two accounts attributed to the diabetes nurse specialist lead to substantially different management regimes: one account requires monitoring every second day or more frequently, virtual daily monitoring when on holiday or when ill. The other account leads to a regime of monitoring about twice

a week, no monitoring on holiday but more frequent monitoring when ill.

Miss J's Self-monitoring Records

96 From our examination of Miss J's written personal records (kept from 12.7.96 to 14.7.97), it is clear that at least up until about the time just before her admission to hospital, she was taking readings mainly at 3 to 4 day intervals.

97 A further notable feature is several extended intervals between some of the recordings, for instance, a 61 day interval between 8 January 1997 and 11 March 1997 when, apparently, no readings were taken. There were several other occasions when intervals of over 10 days occurred between readings.

98 In the 3 months or so before Miss J's admission to hospital, most of the readings were taken in intervals of 5 days or less, in line with the apparent advice. According to the record, the time of readings was varied, ranging between 8.00am and 11.00pm In examining Miss J's records over all the occasions of testing, it is noted that 50 of the 63 recordings (79%) of blood sugar level are at 7, with the remaining 13 (21%) either above or below that value. This degree of consistency is likely to be an artefact of the stepwise system used to grade blood glucose levels using this method. The fact that about 20% of her readings varied from 7 is evidence that she was discriminating the levels where these appeared unusual. There were some occasions where she also recorded a range.

Adherence to the Advice on Self Monitoring

99 From the evidence of Miss J's own records, it would appear that she was adhering fairly closely to the advice described in the submission provided by her brother, not that claimed by the diabetes nurse specialist during the Trust interview.

100 If Miss J was acting incorrectly - and her records are clear enough - it is of concern that no one seems to have called her attention, or that of her family, to this, or sought to educate and motivate her to adopt the correct practice.

101 There appears to be no account of any action taken to modify Miss J's recording procedures (for instance the extended periods in which there were no recordings) or to address the high reading in September 1996 which was followed by an extended interval when no reading was recorded. Presumably such action would have been called for if the regime claimed by the diabetes nurse specialist, in her evidence, was required for proper management.

102 As no such corrective action has been drawn to our attention, then it would be appropriate to assume that Miss J adhered fairly closely to the advice given, or what she had understood to have been advised, and had no reason to believe that she was behaving incorrectly.

103 The account given by Miss J's brother of the diabetes nurse specialist not having concerns about Miss J psychologically or physiologically is also consistent with a view that Miss J was regarded as managing her condition acceptably.

104 The degree of consistency in the levels recorded also appears to have been un-remarked.

105 The clinic must have had some awareness of her record because of the comment that her reading levels coincided with some of the more precise laboratory tests.

106 In sum, the impression given is that the unusual features in Miss J's personal records of her blood sugar monitoring went unchallenged.

Blood Testing on 17 July

107 Miss J's niece, with whom she had a special relationship, gave an account of events on the 17 July that has an important bearing on the contention by the IR panel that she was in "denial".

108 Although Miss J's written record ends on the 14 July, according to the statement of her 17-year-old niece, Miss J tested on two occasions on the morning of 17 July, with the niece having been asked to act as a time-keeper and to give her opinion of the level as Miss J, according to her niece, was unable to make it out precisely.

109 We cannot be certain of the levels Miss J obtained on both occasions of testing on the 17 July. Miss J's niece states that she observed both instances and, when asked to look at the second sample, she - the niece - could not determine the level and in her evidence reports Miss J's statement that it was between 7 and 9. There were 4 occasions before this when she entered a somewhat similar range rather than a single figure in her records. This is the level ("RBS around 7") recorded by her GP on the 21 July and is allegedly based on Miss J's report when he asked her on that occasion.

110 It is perhaps unusual that Miss J could not "read" the level despite two occasions of testing, especially as by this time she had had extensive experience of making readings, including at least two at 11 and others well below. It is possible that it was her physical state - she had been ill for 3 or more days by then and had been to see her GP the day before -

impaired her functioning.

111 That the GP at the consultation on 16 July appears not to have initiated questions about her diabetes, may also have led her to believe that her diabetes and hence her blood sugar level were not of concern in relation to her then present condition. This in turn could be either because she did not know that she should report such findings or because doing so might have led to a disappointing change of plans. This latter possibility is dealt with shortly.

112 This behaviour - taking two readings and involving her niece in the process, of both timing to ensure accuracy and getting her to try and read the value, seems inconsistent with "denial". Further it is difficult to understand why, had she been in "denial" when visiting the GP the day before, she should then be involved in what appears to be a serious attempt the very next day to get a public and accurate reading.

113 However, the possibility of missing the important week-end celebration could be a reason for her not disclosing her high reading. The possibility that she might miss the week-end celebration did not, however, stop her going to the GP on the 16 July nor did it stop her visiting a doctor while at the holiday site.

114 It is also possible that, having been to her own doctor 3 days before with no apparent diabetes-related action, she did not attach any further significance to the reading, whatever its level and therefore did not raise it with the doctor at the holiday park who also appears to not have checked her blood sugar level.

115 In sum, it is noteworthy that Miss J did take action to communicate that she was ill in the period, that she continued testing in a semi-public manner, and we do not have strong evidence that she tried to hide the earlier reading of 11. Her records showed a level of 11 previously without any consequences and there are some grounds for suggesting that for reasons other than "denial", the level of 11 may not have had the significance for her that others might attach to such a reading.

Further developments

116 According to her fiancé, Miss J did inform the doctor at the holiday park that she was a controlled MODY. Again, this is not suggestive of someone in "denial" unless one is trying to assert that she was deliberately setting out to throw him off track.

117 Nevertheless, the earlier high reading was apparently not brought to his attention. Again, one could argue that the lower reading as reported by her niece might have been taken as evidence by Miss J that this was not the problem. She had also seen her own doctor several days earlier and as noted above, he had not pursued anything in relation to the diabetes.

118 Miss J attended the celebration but by early the following morning (20 July) was so ill that her fiancé brought her home.

119 She was seen again by a doctor on the 20 and 21 July. It was on the latter occasion that the note of "RBS about 7" is noted, consistent with the niece's report of the unrecorded reading 4 days earlier. Miss J was hospitalised on the following day.

Impact of Miss J's Deteriorating State

120 It is important to emphasise that Miss J was becoming progressively more ill over the last weeks of her life. It is possible too that the progress of her illness and the discomfort made her increasingly less able to focus on anything other than her on-going state. We know that by the night before her admission, she was in great distress and probably at least confused for periods, if not delirious.

121 Whether or not her mental state was sufficient for her to recollect a reading from a week previously, and associate it with her present state, especially if it had been a "one-off" like the previous "one-off", can be questioned.

122 It would, however, be surprising if her physical deterioration were not accompanied by some deterioration in her ability to function normally in terms of her mental capacities and emotions: she was not just physically ill, it was likely that she was also in great discomfort and mental distress.

The case made by the first consultant: introduction

123 It is not uncommon for diabetes services to have to deal with a number of individuals who do not adhere to the self-management regime prescribed by the service. This failure of adherence is sometimes attributed to "denial" that they are ill, or that they need to conform to the prescriptions for their healthcare. Most, if not all, practitioners in diabetes services, will be likely to have encountered individuals in whom "denial" is regarded as a major reason for poor adherence.

124 At the independent panel review, the first consultant introduced the possibility that Miss J had been in "denial", a view subsequently picked up by and endorsed by the experts assisting the panel. Such an allegation, if supportable, would of course affect the extent to which the first consultant was responsible for what transpired.

125 The first consultant, in his interview with the investigating officer, commented again about Miss J

not wanting insulin and her relief at the diagnosis of MODY as part of the evidence for his claim that she was "in denial" about the transition in her diabetes to a state requiring insulin.

The case made by the first consultant: fear of insulin

126 A fear of acquiring insulin-dependent diabetes was introduced by the first consultant to explain why Miss J did not report the blood sugar level of 11 even though it was logged in her record card. We have no evidence that Miss J expressed such a fear.

127 The comments regarding her reaction to the MODY diagnosis were taken to be evidence consistent with later "denial". However, her relief reactions were both understandable and normal. We can safely assume that most people faced with the prospect of a diagnosis that would require life-long insulin injections would be very pleased at being told that they would not need to do so. Her 'relief at the diagnosis' is most likely a normal, understandable and presumably common reaction. Hence, this is unlikely to constitute a strong ground for implicating "denial".

The case made by the first consultant: transition denial

128 It appears accepted that Miss J was, over most of the period subsequent to the diagnosis, a "compliant" individual about whom there were no concerns regarding her diabetes management and monitoring.

129 The thrust of the first consultant's argument is that she in effect denied her transition from a form of diabetes that does not require insulin to a form that would. He expresses a concern that she did not contact him or his team. The first consultant's view was supported by the IR panel.

130 If we accept that Miss J was a compliant individual, and we also accept, as we must, that by the 16 July she was quite ill, it is not surprising that she did not go to the diabetes service. Her GP did not refer her and did not implicate her diabetes in the presentation; she was ill and likely to have been distressed; and from other accounts of her behaviour, it is likely that she would have attended clinic had she been instructed to do so.

131 Underlying all this, Miss J had not been warned that there was a risk of transition from MODY to insulin dependent diabetes and no questions had been raised as to her previous adherence to the advice she had been given. The evidence is that she did adhere to the self monitoring regime set for her.

Denial as an explanation

132 Miss J's case raises important specific as well as general issues in relation to the use of psychological concepts such as "denial" in attempts by clinicians to understand, account for and manage diabetes and other conditions requiring acceptance of the diagnosis and adherence to a prescribed management regime. The terms "compliance" and "denial" involve assumptions drawn from behaviour, a better term is "adherence" which describes the behaviour only.

133 We accept that it is common in diabetes services for clinicians to see what they regard as "denial". "Denial" is in fact an assumption or inference from the patient's action or inaction, that is, from behaviour, in relation to the diagnosis or some other aspect of care. It is however proffered as an explanation for observed behaviour, why the individual does not appear to take the diagnosis seriously or otherwise adhere to the care prescriptions advanced by the health care professionals who advise on management.

134 Nevertheless, the introduction of psychological explanations to account for what is believed to be a failure to accept the diagnosis or inadequate self-management of illness, is a very serious matter. To begin with, it enables those in positions of power to attribute failure and blame to the patient, thereby exonerating themselves of responsibility for proper care. It colours attitudes towards the patient and, consequently, can adversely influence the motivation of healthcare staff and the adequacy and quality of care provided thereafter.

135 In particular, if "denial" is to be invoked to account for poor adherence, it necessitates consideration of factors in the patient, the illness, the clinicians involved in the patient's treatment and the patient's social environment. In sum, it is not something that should be invoked lightly and then, only on the basis of good evidence gleaned from systematic investigation and the due consideration of alternative explanations.

136 The more neutral term "adherence" is current in the literature on responsiveness to health care advice and is used to refer to the behaviour of individuals who follow the advice given to them by healthcare professionals. Adherence, as a term describing behaviour is different from other terms such as "denial" that are inferences from behaviour. It is recognised that "adherence" allows for variations in the extent of adherence.

137 There are well-established protocols to deal with some of the more common reasons for poor adherence, such as information booklets, special education programmes and the like. It is also well-recognised that despite such standard good practices, there will be individuals who continue to cause concern, those who, while knowing what they

should do, nevertheless fail to act as they should.

138 Under such circumstances, it is important to consider alternative explanations, among which might be something akin to some form of denial. However, given the complexity of human abilities, beliefs, motivations and life circumstances, and the complexity of the concept, "denial" should never be the sole initial conjecture.

139 In dealing with problems of adherence, healthcare staff must attempt to glean reliable evidence on which to base a judgment about the degree of adherence and then reach a decision as to whether or not, in cases of poor adherence, further action needs to be taken.

140 The nature of this action will depend on gaining some understanding of why the individual is behaving in the way they do. In many instances, sensitive, individual-centred enquiry may lead to an identification of the reasons. Even when it is clear that the individual does not believe they have the illness, it is important to try and understand why.

141 On occasions, it takes some time for the mental realisation to become fully integrated into the individual's thinking about themselves and their daily lives. They have to create a new view of themselves and make the corresponding behavioural changes, something that takes some time for most people.

142 To sum up, evidence of clinically unacceptable levels of adherence should be a signal for further investigation rather than what can sometimes be a reflexive labelling of an individual as being in "denial".

Conclusion

143 In Miss J's case I have found no evidence that she was in denial of her illness. It was, in my view, unwise for the IR panel to have introduced this issue. Denial, as I have explained, is a complex concept that does not lend itself to reflexive labelling and should not be advanced lightly as an explanation of behaviour.

Appendix B
Glossary of Terms

Technical term	Meaning
acidosis	an abnormally high concentration of acid in the blood
catheter (urinary)	a flexible tube inserted into the bladder to allow the removal of urine
cerebral oedema	swelling of the brain within the skull
CVP - central venous pressure	the pressure within the central veins returning blood to the heart
dehydration	loss or deficiency of water in body, tissues and blood
fluid balance chart	a chart which records and sums a patient's input and output of liquid on a daily basis
gastritis	inflammation of the lining of the stomach
glycosuria	glucose in the urine
HbA1c - haemoglobin	an indirect measure of the effectiveness of blood glucose ('sugar') control in past two weeks
hyperglycaemia	a high concentration of glucose in the blood
hypoglycaemia	a low concentration of glucose in the blood
hyponatraemia	a low concentration of sodium in blood, usually as a result of a relative excess of water but sometimes a result of salt loss
hypotension	low blood pressure
hypothyroid	reduced thyroid function
ketones	substances arising in metabolism when there is insufficiency of insulin
mass lesion	a solid abnormal appearance on scanning
pituitary apoplexy	collapse as a result of severe pituitary gland failure
subarachnoid haemorrhage	haemorrhage on the surface of the brain
subclavian	under the collar bone
tachycardia	rapid heart beat
type 1 diabetes	insulin dependent diabetes - requires treatment with insulin
type 2 diabetes	non insulin dependent diabetes - controlled with diet and/or tablets

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